EXHIBIT D

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST

AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No: 2:12-MD-02327 MDL 2327
PATTI ANN PHELPS and JAMES PHELPS, Plaintiffs, vs. ETHICON, INC., ET AL., Defendants.	Case No: 2:12-CV-1171

Videotaped Deposition of Catherine A. Matthews, M.D.

General Deposition

March 24, 2016

At 10:30 a.m.

Taken at:

Embassy Suites

460 N. Cherry Street

Winston-Salem, North Carolina

Reported by LeShaunda Cass-Byrd, CSR, RPR

APPEARANCES OF COUNSEL:

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EXAMINATION OF CATHERINE MATTHEWS, M.D.

DEPOSITION EXHIBITS

THE VIDEOGRAPHER: We are now on the record. My name is Len Harris, I am the videographer for Golkow Technologies. Today's date is March 24th, 2016. The time is approximately 10:41 a.m. This video deposition is being held in Winston-Salem, North Carolina, in regards to Ethicon, Incorporated, Pelvic Repair System Products Liability Litigation, Master File No. 212-MD-02327-MDL-2327. This case refers to Patti Ann Phelps, Case No. 212-CV-01171, in the United States District Court for the Southern District of West Virginia, Charleston Division. The deponent is Catherine A. Matthews, MD.

Counsel, would you please identify yourselves.

MR. TEAGUE: Matt Teague for the plaintiff.

MR. ROSENBLATT: Paul Rosenblatt for Ethicon, Inc., and Johnson & Johnson.

THE VIDEOGRAPHER: The court reporter is LeShaunda Byrd and will now swear in the witness.

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CATHERINE A. MATTHEWS, M.D.,
having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. TEAGUE:

Q. Good morning. Doctor, would you please state your name for the record?

A. Catherine Ann Matthews.

Q. Okay. And, Dr. Matthews, are you -- you are here today as a witness. On whose half are you -- excuse me -- on whose behalf are you appearing?

A. The defense, for Ethicon.

Q. Okay. And that would be Ethicon, Johnson & Johnson, the defendants in a general set of litigation that is ongoing; is that correct?

A. Correct.

Q. Okay. And, Doctor, you are here today pursuant to a notice of deposition issued by my office?

A. Correct.

(Plaintiffs' Exhibit 1 was marked for identification.)

BY MR. TEAGUE:

Q. Okay. And I am going to show you what I've

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marked as Plaintiffs' Exhibit 1, which is the deposition notice.

Have you seen that document before, Doctor?

A. I have.

Q. And, Doctor, if you would turn to I believe it's Schedule A on Page 6.

A. (Witness complied.)

Q. You see that?

A. Correct.

Q. Yeah. And, Doctor, have you had a chance to review that before today?

A. I briefly looked through this. I can't tell you all the things that were listed in the schedule, but I have some familiarity with it.

Q. Okay. Did you bring anything pursuant to Schedule A today?

A. I did. I brought all the copies of the records that I've reviewed. As we just mentioned, I have a copy of -- all of my reliance list, and I've got all the articles that I've referenced with my report here in a binder.

Q. And you are referring to a flash drive that was discussed in a -- in a conversation between counsel right before we came on the record?

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A. Correct.

Q. Okay. And, Doctor, have you been deposed before today?

A. I have.

Q. Okay. So I know you understand the ground rules for the most part. I will just say, quickly -- and you are doing a great job of it -- for the court reporter's sake and for our sake down the road, you are probably going to be able to anticipate where I am going on multiple questions, but if you would, just let me get the question out so that it's clear for the record, and then I will do the same for you as you respond. That way the less talking over each other, the better.

A. Sure.

Q. Thank you.

And also, Doctor, if at any point I use a term incorrectly, which is possible, or if I use a term in a way that you don't understand it, if you would just ask me for clarification; otherwise, I'll assume that you understood the question if you answer.

Is that okay?

A. Correct. Fine.

Q. Okay. Doctor, prior to the deposition,

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have you had a chance to review the report that you issued on behalf of Ethicon?

A. Well, yes, after spending many hours writing it, I am certainly very familiar with it, and I reviewed it again before coming today.

Q. Okay. Are there any changes, corrections, anything that you want to point out in it before I use it as an exhibit or ask you questions based on it?

A. No, sir.

Q. Okay. The same with your reliance list, any -- anything that you -- after reviewing it, anything that you looked at and felt like needed to be changed, added to, you know, as we sit here today?

A. There are a few papers in the reliance list that I didn't include within the reference list within my case specific report, but as long as I am allowed to reference all articles on my reliance list, nothing additionally needs to be added.

Q. Okay. So the only distinction would be there might have been a broader set -- or you tell me if I understood you correctly -- there might have been a broader list in the materials that were either cited or used in your general report that you may not have specifically cited again in your case specific report;

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is that correct?
A. That is correct.
Q. Okay. But in terms of the overall list, anything that you felt like needs to be added as we sit here today?
A. It's all there.
Q. Okay. And the same with the other submissions you've made as part of that report in terms of your testimony list, anything that needs to be changed there?
A. No, sir.
Q. Okay. And your CV, have you reviewed that? Is that still accurate and up to date?
A. There are probably a few more publications that was from December, but it's reasonably current.
Q. Okay. While we are on that subject, do you recall any publications as we sit here today that may have come out in 2016 as of, you know -- or say from December 2015 to today's date?
A. I can't recall off the top of my head, but I suspect that there may be one or two publications that actually have -- that were in publication that have now been actually published.
Q. Okay. Thank you.

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Would any of them have dealt specifically with polypropylene mesh or any other procedures used to implant polypropylene mesh?
A. It's possible that one related to mesh used in sacrocolpopexy but not related to suburethral slings or other vaginal mesh.
Q. Okay. So in terms of transvaginal approach, you don't -- you are not aware of anything that has been published from the date that your -- that your publication list or CV was produced to us?
A. Correct.
Q. Okay. That is fine. Thank you.
(Plaintiffs' Exhibit 2 was marked for identification.)
BY MR. TEAGUE:
Q. And while we are at it, I will show you what I've marked as Exhibit 2, and this is expert report of Catherine A. Matthews, MD. Just take a look through that real quick and make sure that we are talking about the same document.
A. Yes, this is correct.
(Plaintiffs' Exhibit 3 was marked for identification.)
BY MR. TEAGUE:

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Q. Okay. And if you would just look at Exhibit 3, is that the -- to the best of your knowledge, that's the reliance list, reference list that you produced to us as part of this litigation?
A. Yes, that is correct.
Q. Thank you.
And am I correct, Doctor, that you are not here on behalf of any individual plaintiff?
A. That is correct.
Q. Okay. And when I mean that, as in you are not a witness that was asked to appear by any plaintiff or plaintiff's attorney, correct?
A. Well, I was obviously asked to review the specific records of Ms. Phelps, but I wasn't asked by her or by someone representing her to appear here.
Q. Correct. That would have been Ethicon's request, correct?
A. Correct.
Q. Okay. And also, while we are on the subject, there are multiple entities within the Johnson & Johnson family.
Are you familiar with the entities or terms Ethicon, Gynecare, Johnson & Johnson?
A. Yes.

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Q. Okay. From time to time, I may lapse in between them. If there is a specific document that is labeled or branded under one of those particular names, I will probably refer to it directly as that.
But otherwise, to the extent you feel an answer is dependent on one or other of those entities, would you please point that out to me?
A. Sure.
Q. And that way I don't have to -- I may still do it anyway, but that way I don't have to repeat three names every time I ask you a question.
A. Sure.
Q. Thank you.
Doctor, what is polypropylene?
A. It's a synthetic material that is used for suture material and used in the construction of mesh.
Q. Okay. Does it have any -- does polypropylene have any uses outside of the medical community?
A. I don't know. Probably.
Q. Okay. You are not aware of any other uses other than the medical community?
A. That is where my area of knowledge is, so that is -- to the extent the material science is known

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to me, I know it as it applies to medicine.
Q. Okay. Doctor, how long have you used polypropylene medical devices?
A. Since I -- if I can recall, since maybe early 2005, possibly late 2004, but somewhere in that range.
I'm sorry, if I can just clarify.
Q. Absolutely.
A. That was, of course, for mesh, not for suture material. I have been using polypropylene suture material since I started as a physician.
Q. Thank you for the clarification.
Do you know of any material differences between polypropylene mesh used in slings and sling kits versus the polypropylene material used in sutures?
And obviously, I am not -- well, I will just leave the question as is. You can answer that.
A. Both --
MR. ROSENBLATT: Object to the form.
THE WITNESS: Both material -- it's the same makeup of material. One is just as a single filament of suture. The other is knitted to create a weaved mesh

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material.
BY MR. TEAGUE:
Q. When you -- I'm sorry. Were you --
A. One -- both -- the same type that is protected in an oxidation sheath are used, so the same material that is used in a suture is used for the mesh.
Q. Okay. Is it the suture material that is knitted to form the polypropylene mesh used for transvaginal implants?
A. I don't believe it's the exact same -- it's made of the same composition.
Q. Okay. While we are on that, Doctor, I was looking at your curriculum vitae. And if you would, in testimony form, I would like to walk through it.
When you graduated from medical school, what did you do -- or strike that.
What did you do after you graduated medical school?
A. I did an OB/GYN residency at VCU Medical Center.
Q. Okay. And what were your responsibilities at VCU Medical Center?
A. As a resident or --

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Q. Yeah, sorry. Let me rephrase that.
As a resident, what were your responsibilities at VCU Medical Center in a general sense?
A. Become an outstanding obstetrician gynecologist.
Q. Okay. Did you do clinical work? Did you see patients at that time?
A. Sure.
Q. Okay. Did you have a mentor or someone who was responsible for your progress as a physician?
A. I had several, but my primary mentor was Glenn Hurt, who was one of the founders of urogynecology in America. And so I was steered down the urogynecology track relatively early in my residency training.
Q. Okay. And then after your residency, did you stay on at VCU?
A. I did. I had a -- I was employed as an assistant professor, but there was an understanding that I was going to do a quote/unquote modified fellowship under his tutelage where we would operate together and do clinic together. So I was being paid as a faculty member, but really was sort of like a

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fellow.
Q. Okay. And your clinical experience during that periods of time with Dr. Hurt, is this what is referenced on your CV as the August 2001 to June 2007 period?
A. Well, he retired in 2004, and so it was the during the three years that he was still on faculty that we worked very closely together. And because he was well renown across the United States, he had a very large referral patent of complex cases of pelvic floor disorders, and so I was the direct beneficiary of his expertise and his reputation.
Q. Okay. Just to get back to the actual experience though.
So from August 2001 to June 2007, were you at VCU, correct?
A. I was there until 2010.
Q. Okay. Got you.
What changed between June 2007 and July 2007? I notice there are separate entities on your CV.
A. I think I changed from assistant to associate professor.
Q. Okay. And, Doctor, going back, during this

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period of time that you were with -- you were an assistant professor, this August 2001 to June 2007 period, how many -- give me a general idea of your work in clinical -- in your clinical -- strike that -- give me an idea of your work, clinical work, versus your academic work at that time.

A. So all of our work was really considered academic, and that even the clinical work involved the teaching of medical students and residents and the accumulation of data that we might have published subsequently. So it was really a blended purpose, which was to do academic clinical work. I had -- you know, 85 percent of my time was directed towards clinical activities that included patient care and teaching, and then I had about 15 percent of my time that was reserved for academic work, specifically working on research projects and so on and so forth.

Q. Okay. During this period of time, and I'll limit it to the August 2001 to June 2007 period when you were an assistant professor at Virginia Commonwealth University, did you use polypropylene mesh for the treatment of stress urinary incontinence?

A. I didn't initially. I was not an earlier doctor of the use of synthetic meshes. My mentor,

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Dr. Hurt, was a traditionalist. He believed in Burch colposuspension and in pubovaginal slings. And at that time I was waiting, both of us were waiting for some better prospective evidence on efficacy. And so from 2001 until 2004, as I mentioned, I conducted numerous procedures with him for management of stress incontinence, both primary and recurrent, but included only Burch procedures and slings, pubovaginal slings.

And then in late 2004, early 2005, after the publication of the longer term outcomes of the landmark Ward Hilton trial, I felt that there was sufficient evidence to adopt something that had equal efficacy and lower complications in my practice. And so at that point, I got additional training from someone outside of my immediate institution and then started performing retropubic clings.

Q. Okay. Were you ever trained by the manufacturers of the polypropylene mesh slings that you used?

A. Never. I don't believe that that is the best way to learn how to do something. I traveled to Europe and did surgery with two -- several surgeons in London and watched their technique, learned the nuances really of placement. And then after feeling

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that, I had satisfactorily observed this, then came back to my institution and did the first several procedures with my other partner, Edward Gill, who was already performing retropubic slings.

Q. Okay. In terms of -- if I understood you correctly, you said that manufacturer-based training is not -- is not the best way to learn it?

MR. ROSENBLATT: Object to form.

BY MR. TEAGUE:

Q. Well, and that is what I'm asking. You tell me. Is it --

A. For me personally --

Q. I -- you know what, Doctor, I didn't mean to interrupt you. Let me ask that a better way.

What do you consider the downside of manufacturer training of products that they -- that they produce?

MR. ROSENBLATT: Object to form.

THE WITNESS: I believe that physicians are best trained through traditional means, which involves medical school education, residency education, fellowship education, and then peer education from colleagues that are

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respected in their educational efforts.

Certainly it is acknowledged that industry has to partner with physicians to conduct training, and that may be perfectly acceptable. For me personally, I didn't want to rely on -- in that relatively early stage in the game and the identification of someone who I didn't know and I didn't necessarily understand what their credentials were, and so I took it upon myself to find somebody that I respected and I felt had good knowledge of the procedure to be able to teach me the correct way.

BY MR. TEAGUE:

Q. Okay. So is -- the decision was personal, not necessarily a categorical criticism of industry training?

A. That is correct. I think, unfortunately, a lot of physicians rely on what is made available to them, but I am very much a firm believer that traditional methods of education should be used whenever possible.

Q. Okay. And if the manufacturer were to

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employ one or more proctors who were experienced in the -- in the implant of the product to teach other surgeons, is that something that you would condone or approve of?

A. I think it's approved as long as the person is well vetted in their abilities and that it's not biased in some way.

Q. Okay. What forms of bias would you consider could exist in that scenario?

A. I think if someone is willing to teach something that they don't really know that much about or haven't really been well trained in themselves, purely for financial remuneration, that would be a biased -- biased proctor.

Q. Okay. Have you reviewed Ethicon's internal documents to see what they taught in their manufacturer-sponsored clinics for specifically stress urinary incontinence products?

A. I don't -- I can't recall specifically looking at those documents.

Q. Okay. What about for any other manufacturer, have you had an opportunity to review the training materials that any other manufacturer of polypropylene stress urinary incon- -- sorry --

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polypropylene mesh intended for stress urinary incontinence treatment has put out?

A. I cannot recall specifically, but it's possible I have. But I just can't recall off the top of my head.

Q. Okay. Do you know Dr. Karram?

A. I do.

Q. Okay. In what sense -- how do you know him?

A. He is, obviously, an exceptionally well respected figure in urogynecology. He has published numerous textbooks and probably over 150 peer review articles. So not only is he a respected surgeon, but he has been a very academic surgeon who is very well published in the field.

Q. Okay. Would you consider him someone who would be a proctor that wouldn't be subjected to the biases that you -- or a proctor or preceptor that wouldn't be subjected -- strike that.

Based on your personal knowledge of Dr. Karram, do you think that he has now or at any time in the past been subject to any form of bias or shown any form of bias based on his relationship with any industry manufacturer?

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MR. ROSENBLATT: Object to form.

THE WITNESS: I don't believe so. I think that if somebody is willing to publish their results where they have clearly evaluated the patient population that they are serving, that they are an outstanding source of information. It's somebody who is not trying to hide their outcomes.

So I think that he is -- he is the exact kind of person who you like to see as a proctor because he's actually been academic in his pursuit of defining the outcomes of the procedure that he is actually teaching. And he has done this for many different companies and for many different procedures.

BY MR. TEAGUE:

Q. Okay. What other companies besides Ethicon?

A. Well, gosh, I can't recall off the top of my head, but, you know, if you look at the vast number of publications he has had, they have included other devices and other products. And so, you know, I think

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that he has got a long track record of publishing outcomes of surgical interventions.

Q. Okay. Now, moving -- again, during this August 2001 to June 2007 period, which products were you using for the surgical treatment of stress urinary incontinence? And I will qualify that to polypropylene products right now.

A. So initially, I used the TVT retropubic sling from Gynecare. And my rationale for that was that that was the device that had been published on in the Ward and Hilton trial, therefore I felt that I was using the exact same material and could reliably expect to have similar outcomes in my patients.

Q. You mentioned the Ward-Hilton trial earlier.

Did I understand you correctly, that was one of the publications that began to move you away from the older procedures you described earlier and towards introducing into your practice the use of polypropylene mesh or retropubic slings?

A. Yes, I think it's fair to say that I've had a long history of trying to practice evidence-based medicine. And if one looks at this product and this mesh, there is more Level I evidence supporting its

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use than any other incontinence procedure. So once the medical evidence started to accumulate that gave me confidence in the scientific efficacy, I felt comfortable altering my surgical practice. But I waited for that information to present itself before changing my surgical paradigm.

Q. Okay. And you would have put that around the 2004-2005 that the medical evidence began to satisfy your willingness to engage in a new procedure?

A. Correct, I wasn't initially satisfied by the very promising but small case series from the Ulmsten and his colleagues. I felt that they could potentially be biased. Who knows if someone has come up with a new idea. I wanted to make 100 percent sure that other people had vetted this before considering it to be potentially an exciting safe new innovation for stress incontinence treatment.

Q. Okay. Thank you.

Did Virginia Commonwealth University, did they purchase and stock the mesh products themselves?

A. They did.

Q. Okay. What else was available besides the TVT Gynecare?

A. I don't know to be completely honest. I do

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know that American Medical Systems at some point started having products on the shelf, and I cannot tell you when that was exactly. I do know that initially the TVT was on the shelf exclusively.

Q. Okay. And now, moving to your time July 2007 to June of 2010 as an associate professor, did you continue using Gynecare TVT products for women that you treated surgically?

A. I think that at some point -- at some point, there was a contractual change at VCU, and they got a lower price for a different type of mesh. And I don't remember if it was a Boston Scientific mesh or it was an AMS mesh, but they were bottom-up approaches that in the technique of insertion of the product it didn't seem dramatically different.

I was somewhat concerned that the mesh properties of those slings were different than the initial TVT, but I was told that by the purchasing people that they were similar enough that the price was sig- -- the price differential didn't warrant potential small differences in the mesh properties, and therefore, you know, we were -- they were going to use the different type of product.

Q. Okay. Did you -- and let's see. So which

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AMS products would those have been?

A. Whatever their bottom-up sling was, sling is. I don't now recall the name. And I could -- I said it's possible it's Boston Scientific. I don't remember. I just remember that there was a cheaper competitor that was brought in --

Q. Sure.

A. -- to the institution.

Q. And I have seen in some records mention of AMS, SPARC and Monarc.

Does that refresh your recollection, any of those --

A. It definitely was not a SPARC because it was not a top-down sling, and it was not a Monarc because it was not a transobturator technique. It was definitely a full length retropubic sling that was from a bottom-up approach.

Q. Okay.

A. So it may have been the Boston Scientific sling for all I know.

Q. Okay. And during that period of time, that those were available, those were the products you used, to the best of your recollection, either an AMS or a SPARC -- excuse me -- either an AMS or a Bard

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product?

MR. ROSENBLATT: Object to form.

THE WITNESS: It was either an AMS or a Boston Scientific.

BY MR. TEAGUE:

Q. I'm sorry, that is my fault.

A. But now that you mentioned Bard, it could have been a Bard retropubic sling.

Q. Okay.

A. I just know that it was a full length retropubic sling, and I'm sorry that I can't recall off the top of my head exactly which product it was.

Q. Okay. No, and that is fine. And just let me clarify that last question.

So at some point, your hospital -- or VCU moved away from Gynecare products to either, and you don't recall which, an AMS, maybe a Bard, maybe a Boston Scientific?

A. For a diff- -- price -- based on a price contracted -- a contracted price that was less.

Q. Okay. That is fair. Thank you.

And so would I also be correct that since those were available, those were the ones you used?

A. That is correct.

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Q. Okay. And looking next at your -- the next period on your CV is July 2010 to June 2015, and that would have been at the University of North Carolina, correct?
A. That is correct.
Q. Okay. And did you also -- did you keep both clinical and academic hours at UNC?
A. I did there because I was the division chief of urogynecology. I had 70 percent of my effort towards clinical activities, again, that included the teaching of medical students, residents and fellows, and then 30 percent of my time was for administration where I was building a division and running a division.
Q. Okay. And what pelvic mesh products, specifically SUI, did UNC stock?
A. So interestingly, when I got to UNC, I can't remember if TVT Exact was on the shelf or not, but I requested that it be pro- -- that it be made available to me because I had moved to exclusively doing these procedures under local anesthesia and IV sedation. And based on the properties of the small needle of the TVT Exact and the fact that, again, this mesh had been the most widely studied in all of the --

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in all of the publications around the world, I felt more confident that that was the right sling to use.
And so on the basis of that, they, you know, allowed me to use the TVT Exact, much to the chagrin I think of the other companies that had their products on the shelf.
Q. Okay. Do you recall whose -- which companies' products were on the shelf at that time?
A. AMS and Boston Scientific.
Q. Both for stress urinary incontinence?
A. Correct.
Q. Okay. And did you use those when those were available, the either AMS or Boston Scientific product? Or I'll say, or did you use those until the TVT Exact became available?
A. I think that they made the TVT Exact available to me immediately, so I don't recall placing -- I certainly -- I certainly used the Monarc sling for intermittent transobturator slings that I placed, so I wasn't averse to using the AMS product. But for the retropubic sling I felt that the TVT Exact was a better product to use.
Q. Okay. Are there any differences between the TVT Exact and the TVT Gynecare?

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A. Yes, two differences. One that I'm aware of, there possibly are others, the -- one of course is the size of the introducer needle, so they went from being a relatively large size needle to one that was very small. And again, because I do these under local anesthesia, the amount of pain that a patient experiences when passing the needle, it, you know, to me felt significantly different. I felt that the bladder perforation might be somewhat lower using a smaller needle.
And finally, of course, the TVT Exact I believe was all laser cut edge, but, you know, I know that that is one of the differences in the later meshes, so I believe that that was how the side of the mesh was.
Q. Okay. Since you mentioned it, to the best of your knowledge, do you know when Gynecare or Ethicon's meshes moved from the mechanical process to the laser cut process?
MR. ROSENBLATT: Object to form.
THE WITNESS: Well, I know that they've always -- they've always made the mechanical cut still available because there was a large cohort of surgeons,

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particularly in Europe, who preferred that based on the premise that you needed to have intercalation of the mesh into the tissue, and having a rougher edge actually facilitated that.
I believe that the laser cut edge was made available sometime between 2005 and 2007, but I can't give you an exact date.
BY MR. TEAGUE:
Q. Okay. Have you reviewed any of Ethicon's internal documents on anything regarding laser cut versus mechanical cut mesh?
A. I have. I specifically asked them to provide me with any internal documents so I could ensure that anything that had previously just been internal was known to the rest of us. So, yes, I have.
Q. Do you recall specifically what you reviewed in that regard, laser cut versus mechanical?
A. I can't tell you who the authors were, but specifically looking at some of the properties under the microscope, once you pulled on the edges, what -- you know, if there were any fragments that were found under the microscope. So I don't know what scientists

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were working with Ethicon, but I have looked at those documents.
Q. Okay. Have you seen any of the pictures in Ethicon's file regarding particles that become separated from the larger body of mesh prior to implantation?
A. Yes, I have seen those.
Q. Okay. What are your opinion of that?
A. I don't believe there is any clinical significance to this finding under a microscope. You know, to me it looks like a tiny piece of suture that no one would make any kind of drama with leaving a piece of one centimeter suture on a permanent material left in a patient. So to have a small particle of polypropylene to me was like having a small piece of suture material. So to me, there is absolutely no clinical significance, and there is no clinical significance that has been outlined in any published literature.
Q. Okay. Are sutures immune from any type of reaction in the body?
A. I would say that when surgeons use monofilament suture, be it delayed absorbable or permanent, it is certainly true that the suture

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material would elicit some foreign body reaction. To the extent that a foreign body reaction is a problem for a patient is very limited. We certainly have experience in pelvic floor reconstructive surgery with patients complaining of pain because of an eroded permanent suture at the vaginal apex that needs to be removed. We have experienced patients describing dyspareunia after native tissue vaginal reconstruction where they have scar tissue that forms around permanent suture.
But these -- to the extent that they are completely immune for patients, no, they are not completely immune. But when you are trying to achieve a surgical result, it's a necessary part of achieving that surgical result.
Q. Okay. So you are not ruling out the fact that a particle loss from a vaginally implanted mesh has the potential of a foreign body reaction?
A. I don't believe that there is any difference in the foreign body reaction if there is particle loss or no particle loss. If the particle is attached to the mesh or it's separated from the mesh, to me, it would induce exactly the same reaction. So to me, it's a -- it's an argument that has no

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scientific basis whatsoever.
Q. Okay. Theoretically, is it possible?
A. Not in any respect. As I just mentioned to you, if you've got a piece of suture material or a piece of -- a particle of mesh, why would -- why would that make any clinical difference to a patient?
Q. I'm asking -- I apologize, but I have to ask you the questions, Doctor. That is what I'm trying to find out.
A. Yeah, I believe that there is no scientific basis for that claim whatsoever.
Q. Okay. So mesh in and of itself, polypropylene mesh, can it elicit a foreign body response?
A. Every single permanent implant elicits a foreign body response.
Q. Okay, but that wasn't my question. Can polypropylene mesh elicit a foreign body response?
A. As far as polypropylene is a permanent material, of course, it can -- of course, it can and will elicit a foreign body response.
Q. Okay. So that would also be true of any particles that were lost from polypropylene mesh, they have the potential or can cause foreign body

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responses?
MR. ROSENBLATT: Object to form.
THE WITNESS: Sure. As I said, if the particle is attached to the mesh or detached from the mesh, I would expect it would have the same properties and elicit the same reaction.
BY MR. TEAGUE:
Q. Okay. And I'm sorry, lastly, when you moved to Wake Forest, again, give me just a general description of your clinical time versus your academic time?
A. So I'm a professor that has a joint appointment in urology and OB/GYN. 90 percent of my time is attributed to clinical activities and 10 percent to administrative responsibilities. I'm the codirector of an integrative public health unit. Again, I have the same responsibilities of teaching medical students, residents. And I am working on an application, we have applied for a fellowship here in female pelvic medicine.
Q. Okay. How often in your practice -- and I'm limiting it to Wake Forest -- how often do you implant polypropylene mesh for the treatment of stress

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urinary incontinence?
A. Can you clarify, what do you mean by how often? On the basis of a week, a month?
Q. Yeah, sure. Any -- any -- per year, per week, per month, whatever you are comfortable -- whatever would be the easiest for you to translate for us.
A. Well, at the moment, I'm still establishing my practice here, so my surgical volume is not yet what it will be, you know, probably six or 12 months from now.
Q. Okay.
A. So I have probably implanted five synthetic slings since I've worked here since December. But at UNC, if I used that as my comparator that was most recent, I would implant at least two or three slings a week.
Q. And those would be polypropylene retropubic slings?
A. The vast majority. On occasion, a transobturator sling in a patient who I believe would be at increased risk of a voiding dysfunction or have intraabdominal adhesive disease. But the vast majority were full length retropubics.

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Q. Okay. Have you ever used mesh for the treatment or repair of pelvic organ prolapse?
A. I do, with robotic sacrocolpopexy and for recurrent anterior and apical wall prolapse in a patient who is not a good candidate for sacrocolpopexy.
Q. Okay. How often do you use -- have you ever used the transvaginal approach for pelvic organ prolapse repairs?
A. Yes, as I just mentioned for recurrent anterior and apical prolapse with someone who is not a candidate for sacrocolpopexy.
Q. Okay. Do you still use autologous slings for any of your patients who need surgical intervention for stress urinary incontinence?
A. I do, but rarely. It's rare that a patient will elect that procedure. We offer it to every single woman who has stress incontinence. We offer vertical for suspension, autologous vaginal sling and synthetic midurethral slings to every patient. It's very rare that an individual would choose that. It is my recommendation to perform a pubovaginal sling in someone, for example, who I believe has got specific risk factors for a mesh-related complication, patients

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who have had radiation therapy, people who have suprapubic underlying pain disorder. Patients such as those, I might make a specific recommendation that they have a pubovaginal sling.
Q. Okay. What are the benefits of -- and give me, when you are describing to a patient, what do you describe is the benefits of a pubovaginal sling?
And I'm sorry, let me back that up a second. Would you define for us just so we have it on the record what do you consider a pubovaginal sling?
A. The pubovaginal sling is characteristically an autologous fascial sling that is placed at the bladder neck that is designed to elevate the bladder neck at rest and during stress. It's a procedure that requires harvesting fascia from either the lateral thigh or the abdominal wall, as cadaveric fascia of the materials is not found to be as good as autologous fascial.
Q. Okay. Now, using that definition, that procedure, what do you advise your patients are the benefits of that procedure?
A. So the only benefit of that procedure is that there is no -- there is no risk of mesh exposure or erosion. That is really the only benefit. And

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that is -- that is evidenced through numerous clinical trials of the best medical evidence. There is head to head worse subjective and objective outcomes. There is a higher rate of surgical complications. There is a much longer recovery time. There is a much higher rate of voiding dysfunction. There is a higher rate of pain.
So all told, the only difference is that you don't have to deal with a foreign body being present that can have erosion or exposure.
Q. Okay. And, Doctor, while I certainly appreciate the answer, if you would just for foundation and for some other legal reasons, you kind of jumped ahead to -- I assume some of those were also the risks that were involved in -- or what you would consider negatives involved with that surgery?
MR. ROSENBLATT: Object to form.
THE WITNESS: Correct, the risks.
BY MR. TEAGUE:
Q. Okay. Really, I had only asked for the benefits at that time. So if you would just kind of slow down a little bit and just stay with me so I can put this together. Do you understand --
A. Sure.

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Q. -- foundationally? So that the record is clear.

Okay. So I will give you, you know -- am I misquoting here, did you also -- the last few things that you described in terms of there was no mesh erosion, and then you listed some things that I interpreted as being either complications or risks associated with -- with that particular surgery. Did I understand you correctly?

A. Correct.

Q. Okay. What about in terms of what other non-mesh procedures, surgical procedures, do you use to treat stress urinary incontinence?

A. So the two others would be the Burch retropubic colposuspension and then paraurethral bulking injections, which I use probably least commonly but certainly there are circumstances when it may be indicated.

Q. Okay. Now, I'm going to give you a chance to answer both, so just stick with me here on this one.

Now, when you are advising a patient on the benefits of a Burch procedure, what do you tell them, typically?

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A. That, again, they are not at risk for a mesh exposure or erosion. They are at risk for permanent suture erosion, but they are not at risk for mesh exposure and erosion.

Q. Okay. What about in terms of efficacy? I mean, do Burches work?

A. They do, but they don't work better than a midurethral sling, so I can't --

Q. Okay.

A. -- advise the patient that she would have a better outcome. And certainly, I might -- I might say to her that really according to the results of the randomized trial of Burch versus pubovaginal sling that she is likely to experience worse outcomes than a midurethral sling with a decline in efficacy over time.

Q. Okay. So that is what I was going to ask you next. What do you consider the adverse events or complications associated with Burch?

A. So the adverse events, I think that you can cluster into those related to the perioperative period and then of course the longer term outcome. So in the perioperative --

Q. Okay, sure, let's break that up. So, yeah,

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I'm sorry, it sounds like you are already doing that.

So give me the perioperative period first.

A. So perioperatively, because they -- the vast majority of women still have an abdominal incision, and with the abdominal incision they are the risks of wound-related complications. Bowel injury at the time of surgery is at highest 3 percent.

Bladder injury ureteral kinking, bleeding from the retropubic space, urinary tract infection, post-operative voiding dysfunction, length of stay in the hospital, need for catheter use, are all relatively significant for patients undergoing Burch and higher than for a midurethral sling.

And then post-operatively in the delayed prolonged post-operative period, a decline in efficacy over time has been evident and very clearly evident in several studies.

And then, of course, the development of pelvic organ prolapse is a consequence of deviating the anterior vaginal wall, which is a significant post-surgical complication that in many women requires a fairly complicated surgical intervention.

Q. Okay. When you are describing periurethral bulking to a patient, what did you describe as the

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benefits?

A. The primary benefit is it can be done in the office under a local anesthetic.

Q. Okay.

A. The risks of voiding dysfunction are relatively low, but unfortunately, the efficacy is low and declines over time very predictably.

Q. Okay. Just for the record, for the jury, for anyone else who may look at this down the road, periurethral bulking is not a surgical procedure per se, is it?

A. Well, I believe that any time I'm doing something invasive to a patient, it's considered a surgical procedure. If a woman -- you know, if your wife is having a needle stuck around her urethra and something injected, I would imagine that you would consider it to be a surgery.

Q. Okay.

A. It doesn't involve suture material. It doesn't involve -- involves a foreign body. But it's -- doesn't involve mesh material. But it is a surgical intervention.

Q. What foreign body does it involve?

A. Well, it depends on what you are injecting,

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so --
Q. Give me some examples.
A. Calcium, the Macroplastique beads, I can't remember exactly what is -- what the makeup is of those, but it's certainly a foreign body.
Q. Okay. Do you ever use periurethral bulking as a say first step in the treatment -- or give me an idea, what would be your sort of least invasive to most invasive list of things that you would offer a stress urinary incontinence patient?
A. Well, least invasive is pelvic floor physical therapy, followed by an incontinence pessary, and so those two options are offered to every single patient.
Q. Okay. Can I just stop you right there? Are there any -- are there any adverse events associated with pelvic floor therapy?
A. Your pocketbook, if you want to pay money for something.
Q. Okay. Other than -- but you have to pay money for all of these procedures, correct?
A. That is correct. But if you look at the randomized trial that was published in the New England Journal of Medicine that looked at women who were

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randomized to physical therapy versus having a sling, the crossover rate from the PT group to the sling group was very high, so basically, saying that in people that have significant stress incontinence, they're going to go on to need sling, and that's the far preferred intervention. So actually it ends up being cheaper just to do a sling on the front end because the vast majority of people who actually have physical therapy go on to need the surgery anyway.
Q. Did that -- did that study factor in the cost of women who have slings and then need erosion -- or subsequent intervention to treat, pick your topic, erosions, pelvic pain, anything else along those lines?
A. Well, the study wasn't designed as a cost effective analysis. I'm just pointing out that rationally if a large percentage of patients have to have duplicate procedures, it's very likely that the costs incurred are going to be higher. And certainly, in that trial, they reported on all the complications that were endured by patients who underwent the sling, and it's certainly true that as I started out by saying physical therapy is the least invasive and has no complications associated with it.

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Q. So just so I'm clear, a woman that has a retropubic sling, for instance, and then later for whatever reason has complications arising therefrom, she will also endure the additional cost associated with the treatment for that procedure as well?
A. Sure.
Q. Okay. And in terms of your role as a physician, would the -- I mean, how often do you actually look at the economic consequences of the procedure itself? In other words, do you advise or not advise a patient to do something based on price alone?
A. I absolutely don't advise based on price alone, but I am sensitive to women who have significant economic restrictions. So, you know, for example, a patient that is paying -- would pay for everything out of pocket, I would never recommend a pubovaginal sling or a Burch procedure because they are going to need to be in the hospital, and that is the thing that has the majority of expense. So even while the implant itself is more expensive, the perioperative expenses may be significantly lower.
But I think that the biggest thing that motivates me when talking to a patient is the degree

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of their symptom bother and the likelihood that my intervention, whatever I recommend, is going to work for them.
Q. Okay. At Wake Forest, how much does a typical retropubic sling implant cost to a patient -- or well, without getting into, you know, insurance versus not insurance, what is the typical price of that surgical procedure?
A. So the -- the sling itself does vary according to its if contracted or not, but anywhere between 700 and a thousand dollars.
Q. Okay. And then there would also be the surgeon's time, correct?
A. Correct, I would hope that I would get paid --
Q. Yeah.
A. -- for what we're doing.
Q. I mean, certainly, no one is working for free at a hospital, correct, other than the candy stripers I guess if that still exists?
A. Right.
Q. So do you have a -- do you know the figure all in, hospital stay, even if it's, you know, 30-minute non-invasive, let's say for retropubic

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slings, between the hospital cost, the mesh cost, the surgeon cost, nurses, anesthesia, anything else that may be involved? What I'm asking is do you know what the total overall price of that all in would be?

A. I don't know Wake Forest because I've only been there since the end of November, but I can tell at UNC that it was around $4500.

Q. Okay. Thank you.

Doctor, for Exhibit -- I'm sorry -- Exhibit 2, your expert report, did you write that entire report yourself?

A. I did.

Q. Did you have anyone else help you with that report?

A. Butler Snow sent me a list of all of the items that they wanted me to cover, so I had a quote/unquote outline. But the contents -- other than the outline, nothing else -- nothing else was provided to influence writing of the report.

Q. Sure.

A. And I obviously, communicated with them to -- with a long list of potential references to send me, a digital library and a hard copy library of the articles.

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Q. What was the purpose of having them submit you the articles?

A. Just because I have -- you know, I have these articles from doing literature reviews throughout my academic career, and it takes time to collate them into one place. And so instead of having to pull all of these articles from my office from multiple different folders, it was easier just to have them send me one binder that had everything neatly organized.

Q. Okay. Do you know -- have you submitted total hours tabulation for the time it took you to review, research, and write this report?

A. I did.

Q. And how much time have you invested so far?

A. 25 hours for the writing of the report, and then there were I think maybe four additional hours for this -- the specific report on Phelps. And I'm recalling that by memory. I believe it's correct. But certainly, we can send you copies of bills that I submitted.

Q. Okay. Would that -- would the 25 and -- hours and the four hours you just referenced, would that include any background research or case-specific

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medical file research that you did?

A. What do you mean background research?

Q. In other words -- well, let's say for the four hours -- and I don't want to mix them up too much here -- but for the case specific, did you actually review her medical records?

A. Yes, and so that was -- so the four hours was spent just writing the report. There were -- I spent additional hours, I think maybe -- contrary, it was six hours maybe reviewing all of these two big binders of medical records and depositions. So absolutely I reviewed the notes from her care.

Q. And that is the same question I have for the 25 hours for the general work, does that include -- is that just the writing of the report, or would that be review of literature that you needed to refresh your recollection on some things? And I am just giving you examples. In other words, was that just strictly the writing of the report or was that all in 25 hours?

A. All in 25 hours. I mean, it took -- it took -- a lot of that 25 was reviewing individual papers to craft the arguments that I felt were necessary to make. And because there's so much robust

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evidence in favor of midurethral slings, there is a lot of information to go through.

Q. Okay.

MR. TEAGUE: We've been going a little over an hour. Is everybody still good?

(Off the record.)

MR. TEAGUE: Okay. Sure. Are you all -- yeah, we'll go off the record for a minute.

THE VIDEOGRAPHER: I've got 25 minutes left. I could stop this now and start a new one or just go ahead. I can just end this one.

MR. TEAGUE: Okay.

THE VIDEOGRAPHER: This is the end of Videotape No. 1 in the deposition of Catherine Matthews, MD. The time is 11:35 a.m. We are off the record.

(Recess taken.)

THE VIDEOGRAPHER: We are back on the record. This is the beginning of Videotape No. 2 in the videotape deposition of Catherine Matthews, MD. The time is

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11.40 a.m.
BY MR. TEAGUE:
Q. Dr. Matthews, did you have anyone else -- and again, I'm referring to Exhibit 2, your expert report -- did you have anyone -- any non-lawyers assist you in either the research or drafting of your report?
A. No, it took one very long, painful weekend.
Q. Okay. And you were paid for your time, correct?
A. Of course.
Q. And you were paid at the rates that you disclosed in your -- in your report?
A. That is correct.
Q. Okay. Remind me again, Doctor, you may have discussed this I think prior before. But did you have a list of either topics or -- let's just use that word -- did you have a list of topics that you provided to Ethicon in terms of things that you wanted internal documents for?
A. Yes. I asked them about materials that they submitted to the FDA and about studies that they had done internally. My greatest fear was that there was some internal -- you know, I said for me my -- the

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company's obligation is that they truthfully provide information that is internal to physicians, and I wanted to make sure that there was no hidden information that was not available to us that would surprise me.
Q. Okay. Were you provided any Ethicon records from the medical -- from the R&D file, or research and development file?
A. I can't recall exactly what records from what file were provided. But my general request was to provide me with their research information and what had been submitted to the FDA, and that is what I reviewed.
Q. Okay. Did you have, for lack of a better word, unfetterred access to review their files on your own?
A. I didn't have an interest in reviewing all of their files. I didn't have the time. I asked Paul to provide me with what I had asked, and he was willing to give me whatever I asked him to provide me.
Q. Sure. And certainly, I am not implying anything negative about counsel here. But how do you know as a physician, how do you know Ethicon didn't cull or edit what they gave to either your counsel or

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to you to review?
A. I have no idea if they did. I made a request, and I got a reply, and that is all I can tell you here today.
MR. ROSENBLATT: We'll give her all 25 million documents next time.
MR. TEAGUE: Do I have all 25 million yet?
BY MR. TEAGUE:
Q. Let's see. Did you receive in the doc- -- strike that.
In the documents that you received from Ethicon, did you have any MAUDE or adverse event databases provided?
A. I didn't get that from them. I've obviously -- as a board member for AUGS, we were fully aware of the MAUDE database and data from that in drafting the AUGS position statement on midurethral slings, and so that was information that was known to me well beforehand.
Q. Okay. As a clinical physician, do you have hotlines or numbers that you can call for -- and I will use Ethicon for now -- that you can call Ethicon and ask their medical affairs team questions?

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A. I don't off the back of my -- of the -- you know, I don't off the top of my head know of a number. But with a smartphone I'm imagining I could get hold --
Q. Right.
A. -- of someone pretty quickly if I needed to.
Q. Well, let me ask you this: In your clinical practice, have you ever contacted a -- and I'm not limiting it to mesh -- but have you ever contacted a medical device manufacturer to ask them specific questions about use, complications, indications, anything along those lines?
A. I would never rely on a company to provide that information to me. I have actually written a very scathing article about this very point of not relying -- you know, there have been some catastrophic outcomes where people have relied on purely on industry to provide them information, because that is not the avenue of training that is accepted and appropriate. We in the medical field have to rely on unbiased information from our medical training and then to get appropriate training from colleagues if you didn't learn that stuff when you were a trainee.

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So, you know, I -- I cannot tell you an example where I've relied on a company to provide me information. If I needed information about a specific product, I would call a colleague who had used it who I respected and ask them their opinion and have them walk me through any specifics of something.

Q. Okay. Are you aware, Doctor, that Gynecare, Ethicon and Johnson & Johnson make more than just retropubic slings?

A. Sure.

Q. Okay. They also make polypropylene mesh products intended for use in pelvic organ prolapse, correct?

A. They do that, and I believe they also make it for hernia use.

Q. Okay. And they also make transobturator slings, correct?

A. Correct.

Q. Doctor, what is your understanding of the 510K process?

A. So a predicate process by which devices can be approved without premarket clinical studies on the basis of similar -- similarity to an existing product that is approved.

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Q. Okay. And was -- to the best of your knowledge, was the Gynecare TVT introduced that way to the U.S. market?

A. It was.

Q. Okay. And you said without preclinical studies?

A. Correct.

Q. Okay. Tell us what you mean by that.

A. So a preclinical study would be a -- usually a randomized trial or a significant prospective case series of collecting information, publishing it and then getting it submitted on the basis of those reports. So typically, yeah, it would require evidence -- like a pharmaceutical trial of a new drug, they require documented efficacy and side effect evaluation before something is approved.

Q. Okay. So Ethicon or Johnson & Johnson did not have to go through that process for the Gynecare TVT sling? In other words, they did not have to do clinical trials prior to approval, correct?

A. They didn't have to, yet trials were done.

Q. By Ethicon?

A. By people that both affiliated with Ethicon and those that were not affiliated with Ethicon. So

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it was, obviously, approved in Europe -- or manufactured and used in Europe before it was approved in the United States, and studies were conducted, both studies that were supported by Ethicon and then others that were not.

Q. Which studies did Ethicon support, to the best of your knowledge?

A. Well, Ulmsten, of course, had a close relationship with Ethicon. You know, he was trying to find support for something that he believed was an innovative solution to a very common problem. And there was a partnership between him and Ethicon in the -- both the design and the production of the product. You know, he originally developed the six intravaginal sling plasty, and that was modified to some degree by Ethicon to produce what we now know as the TVT retropubic sling.

Q. Was Ulmsten an Ethicon employee to the best of your knowledge?

A. I don't know if he was an employee. He certainly had contractual relationships with Ethicon and was paid by them. He was paid by them both for royalties of the device and then for publication data.

Q. Okay. Do you consider -- have you -- or

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how in your mind would you rule in or rule out the possibility of bias, what you discussed earlier, in that relationship?

A. Yes. I think that it's very fair to say is there bias, and I believe that any individual that has significant financial remuneration can have significant bias. And that is why I want us to look at independent observers who did not have those financial relationships to see if their results were the same, both in terms of efficacy and in terms of complications. And it's exactly why I didn't jump on the bandwagon early on but waited until other people could corroborate those initial very positive results.

Q. Okay. You would agree with me that Ulmsten would directly benefit financially from the adoption of his process and use in commercial sales in the United States or Europe?

A. For sure.

Q. Okay.

A. I think that to some degree someone who came up with a brilliant new design, he deserved to be -- to not have all the credit go to just a company. I think that physicians have not been able to necessarily partner in a beneficial way always. You

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know, they may come up with some brilliant idea, and then a company basically snatches it up. And he seemed to manage to structure things so that he really would benefit.

Q. Okay. Have you reviewed the contract between him and Ethicon?

A. I have.

Q. Okay. Do you know how much -- do you know any financial figures, what he benefited financially from Ethicon's sale of TVT devices?

A. It was over a million dollars. I don't know to what extent it was over a million, but it was definitely over a million dollars.

Q. Okay. Do you know how much money to date in any form, whether it be, you know, including manufacturing costs, excluding manufacturing costs, do you know how much -- have you looked at or have you determined how much money Ethicon has made from the sale of their TVT devices alone?

A. I don't know, but if there have been 3 -- more than 3 million slings implanted, and you multiply that by a thousand dollars a sling, then, you know, you come up with a large number.

Q. Okay.

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A. I certainly know that no sale, no profit will be able to pay for the costs of litigation that have been set aside as -- with the example of AMS. It's very clearly apparent that the billions of dollars that have gone towards litigation certainly far outnumber any profits they would have made.

Q. Doctor, with all due respect, I'm going to move to strike that entire response from the record because that is not what I asked you, was it? Did I ask you what the financial incurrence --

A. You asked me what money they could -- you asked me what money they made --

Q. I asked --

A. -- and so in the --

Q. No, Doctor, what I asked you was are you aware --

MR. ROSENBLATT: She -- let --

MR. TEAGUE: No, I'm not because --

MR. ROSENBLATT: -- let her finish answering the question.

MR. TEAGUE: No, she is not answering the question. She is speaking without a question on the table.

BY MR. TEAGUE:

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Q. What I asked you, Doctor, was -- and I'm just asking you -- do you know what Ethicon -- do you have any idea what their -- what their sales have been of the Gynecare product? I didn't ask you about AMS at all.

MR. ROSENBLATT: Objection, asked and answered.

BY MR. TEAGUE:

Q. Okay. So -- well, let me ask it again. And let me specifically say, Doctor, without bringing in AMS that I didn't ask you about at all, I'm just asking a simple question. Do you know how much money -- and you may not know, I'm just asking you -- do you have any idea how profitable or how much money Gynecare, Ethicon, TV- -- J&J make from the sales of their TVT product?

MR. ROSENBLATT: Object to form, asked and answered.

THE WITNESS: I can tell you on the basis of more than 3 million slings implanted, based on whatever percentage Ethicon has, it's a large figure if you multiply that by a thousand dollars a sling implant.

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BY MR. TEAGUE:

Q. Okay. That is fair.

A. Can I ask that you not raise your voice to me if you have an objection about something?

Q. Yeah. If I did, I apologize. But can I ask that you not dovetail answers that are unresponsive into your responses to my very direct questions?

MR. ROSENBLATT: Matt, she -- she is going to answer the way she feels is appropriate and accurate, and if you don't like it, I'm sorry, but she is going to answer --

MR. TEAGUE: That is fine.

MR. ROSENBLATT: -- how she feels is best to respond.

MR. TEAGUE: That is fine. I will continue just to strike it on the record.

BY MR. TEAGUE:

Q. Doctor, has any Ethicon polypropylene mesh product ever been removed from the market?

A. Removed in what respect?

Q. How do you understand that question?

MR. ROSENBLATT: Object to form. Are

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you talking about the FDA or are you talking about --

MR. TEAGUE: No, I'm not answering questions on the record. I will --

THE WITNESS: I'm asking you to clarify because I don't know what you mean by "removed."

BY MR. TEAGUE:

Q. That is fine. That is fair.

Doctor, are you aware of Ethicon taking any of its own polypropylene mesh products off the market?

A. Yes, I'm aware of them re- -- well, no longer manufacturing and no longer selling the Prolift vaginal mesh insert. To what extent it was removed, I don't know if it was removed. It was -- the manufacturing ceased, and it's no longer available for implantation.

Q. What is your understanding of why that took place? Why was the Prolift taken off the market?

A. I don't have -- I don't -- I have never placed one, and I am not here to provide evidence about vaginal mesh. And so I'm not rendering an opinion about that.

MR. ROSENBLATT: Yeah, I'm just going

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to object to form to outside the scope.

BY MR. TEAGUE:

Q. You are not here to give an opinion about vaginal mesh?

A. I am not here to give an opinion about vaginal mesh for use in prolapse repair.

Q. Okay. That is fine.

Doctor, are there any other products that you can think of that Ethicon has taken off of the market, or stopped manufacturing to use your words?

A. I am not aware of any. I am -- there may well be. I'm not aware of any.

Q. Okay. Do you know if the Prolift was introduced by the 510K process?

MR. ROSENBLATT: Object to form, outside the scope.

THE WITNESS: I'm aware that all vaginal meshes have been introduced through the 510K process.

BY MR. TEAGUE:

Q. That would be true for every product, Ethicon has manufactured for the use included for -- that includes polypropylene mesh?

A. That is correct.

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Q. So, Doctor, it's fair to say that sometimes mesh products introduced through the 510K process are later removed from the market for whatever reason?

A. Sure.

Q. Would safety, efficacy be involved in that decision?

A. I cannot comment on what the decision was -- that Ethicon made. That was not my decision to make, and I have no idea what they considered in making that decision.

Q. Is the TVT Secur still on the market?

A. I don't believe so. I never have placed one of those either, so I am -- I am not aware if it's still available. If you tell me it's not available, I wouldn't be surprised.

Q. No, I'm just asking if you know one way or the other.

A. I don't.

Q. Okay. Doctor, have you ever advised or consulted a product or pharmaceutical manufacturing company on the 510K process?

A. No.

Q. Okay. Do you have any involvement in the 510K process other than review of records?

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A. No.

Q. Doctor, have you ever advised or consulted a company -- and don't let my terms limit you -- have you ever had any involvement with any pharmaceutical or product device manufacturer in obtaining clearance through the FDA through a process other than the 510K?

A. I was involved with a company called Pelvalon in the manufacture of an intravaginal device for fecal incontinence that was introduced through the FDA in a non-510K process.

Q. Is that -- has that product gone to the market in the United States?

A. It's been FDA approved, and it's currently in production to become commercially available.

Q. When was that FDA approved?

A. Last year.

Q. What was your role in the process?

A. I was one of the principal investigators for the evaluation of the efficacy of the device, and I now serve as a consultant on their advisory board.

Q. Speaking of which, so you just -- and what was the name of that company, I apologize?

A. Pelvalon.

Q. Pelvalon. So excluding Pelvalon, what

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other -- well, let's start with this: What other mesh manufacturers have you worked with?
A. I worked with AMS in trying to develop a better Y-mesh for abdominal sacrocolpopexy, and that is the only company that I've worked with in terms of any product development.
Q. And just for the jury or anyone else that watches this who may not have an understanding of medical literature -- or sorry -- medical procedure, what is the Y-mesh used for?
A. It's used for abdominal sacrocolpopexy for apical prolapse.
Q. And in a nutshell, how does that differ from say the implant of a transvaginal approach for addressing the same problem?
A. So it's introduced abdominally, not vaginally.
Q. Okay.
A. It was not included in part of the warnings from the FDA in either 2010 or 2011.
Q. To the best of your knowledge, Doctor, when was the Gynecare TVT product introduced to the U.S. market, in terms of the year?
A. I think it was 1998, but I could -- I could

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be wrong about that. But late 1990s.
Q. Okay. And at that time, were you in med school, or were you a resident already?
A. I was a resident.
Q. During your residency, did you write any papers or evaluate the Gynecare TVT product or 510K process?
A. No.
Q. Okay. Have you ever worked for the FDA in any capacity?
A. No.
Q. Have you ever been on an FDA advisory committee?
A. No.
Q. Have you ever assisted a pharmaceutical or medical device company in the production of -- I'm going to use the term loosely -- literature or labeling for benefits, indications, contraindications for their product?
A. No.
Q. Okay. And that would be the same for the fecal incontinence device that you discussed earlier?
A. Correct.
Q. Okay. Who is responsible, to the best of

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your knowledge, in the fecal incontinence device, who is responsible for producing that information?
A. I believe that in terms of the FDA, there are FDA requirements as to the company in terms of constructions for use and generally accepted complications from the device.
Q. Okay. And that would be true -- or do you have any reason to believe that requirement wouldn't be true in the sense of the Gynecare TVT, that the responsibility would be Ethicon's and Johnson & Johnson's to at least form the basis -- or strike that. Strike that. That was a bad question.
Do you have any reason to believe that the same obligation doesn't run to Ethicon for the Gynecare TVT in terms of the IFU?
MR. ROSENBLATT: Object to form.
THE WITNESS: Every company has the same set of requirements that are produced by the FDA.
BY MR. TEAGUE:
Q. Okay. Do you, as a clinical physician, do you -- is it your belief -- or strike that.
As a clinical physician, do you believe there is anybody in a better position to know the

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indications, contraindications, risk and benefit of a product than the manufacturer itself?
A. 100 percent I believe that there are people that are better equipped to know those.
Q. Okay. Give me some examples, if you would.
A. Companies are not in the business of taking care of patients. They don't see patients in follow-up in every office across the country. They don't -- they are not there as implanting surgeons. They certainly have material scientists that work for them, but they are not -- they are not available to -- to see the patients or do the surgery.
So I would say that surgeons are the ones who are most equipped to evaluate and report on outcomes of an intervention.
Q. Okay. In terms of legal status, just to use a term loosely, are you required -- does -- is that the way the -- does the FDA place responsibility upon the surgeons or the manufacturers to know information about that product?
MR. ROSENBLATT: Object to form.
THE WITNESS: Certainly, the FDA puts responsibility on the manufacturer in the IFU to detail any -- the generalities of

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any specifics of their particular procedure, and they require them to disclose the reasonable accepted risks of the procedure.
BY MR. TEAGUE:
Q. Okay. Doctor, have you ever, in a clinical setting, treated a patient for a mesh complication? And I will break that down more later, but just right now for a global term. Have you ever treated a patient for something you believe was a mesh complication?
A. Sure.
Q. Okay. If you would, just kind of give me some general examples.
A. I have treated patients for mesh exposure. I have treated patients for voiding dysfunction. I have treated patients for dyspareunia. I've treated patients for groin pain. I have treated patients for thigh pain. I've treated patients for retropubic pain. I have treated three patients with bladder erosion of mesh, and I have treated two with urethra erosion of mesh. Not from people that I implanted the mesh on but who were referred into my practice.
Q. Okay.

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A. Those are, I think, some general -- general things.
Q. Okay. Were those -- and I'm sorry -- were those limited to -- is that all mesh, or is that limited to SUI TV -- I'm sorry -- to SUI related mesh products?
A. All mesh.
Q. All mesh. Okay.
What problems have you personally treated for stress urinary incontinence polypropylene implants?
A. Mesh exposure, mesh erosion, voiding dysfunction, pain. Those are the predominant things that I can recall.
Q. Were any of those patients where you had done the actual implant?
A. A few of them, yes. I can probably quote a .5 to 1 percent rate of mesh exposure in the vagina for patients that I have implanted the sling, so in my career I think I've removed two -- treated two of my personal patients for mesh exposure in the vagina. I have not personally had to treat a patient of mine whom I implanted the sling for bladder injury, urethra injury or bowel injury. I treated one patient who had

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groin pain following a transobturator sling. And I've treated one who had retropubic pain after a TVT. And both of those patients resolved their pain with medical management and physical therapy without explant of the sling.
Q. Okay. While we are on that subject, have you ever performed a follow-up surgery to an SUI polypropylene device?
A. Yes.
Q. Okay. And if you would, give me just some examples of -- or what types of surgeries have you performed to correct a complication from a stress urinary incontinence polypropylene implant?
A. So I have done sling release for postoperative voiding dysfunction, two of my personal patients that I can recall over the years. I have removed mesh, suburethral mesh that was not exposed but patients had pain with intercourse, and there was a palpable band across the vaginal fornix that I believed was responsible for their pain, and these were people who had transobturator slings. I have taken -- I have taken -- done bladder mesh removal in three or four patients. And I have taken mesh out of the urethra twice.

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Q. Okay. Without being insensitive, Doctor, did you consider or was it your medical opinion that you had placed the slings wrong in those instances?
A. Even those cases that I had placed, as I told you before, I'd only had two cases where I placed where the mesh was --
Q. And I'm sorry, you are right, and I asked the question poorly.
In the cases that you were the implanting physician and there was later a complication, did you consider that -- did you make a determination as to whether it was an implanter error, in other words your fault, or whether it was something to do with the mesh?
A. In both cases of voiding dysfunction, I absolutely believed it was my error that the sling was placed with too much tension at the time of surgery, and as soon as it was released, there were no further problems. In the patients with mesh exposure, I don't think it was my implanting error because I do it the same technique every time. But both patients were smokers, which is a known independent risk factor, so I believe that the interaction between the material and the host was what likely created the -- the

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exposure.
Q. Has Ethicon or Gynecare or Johnson & Johnson ever contraindicated any of their mesh sling products for smokers?
A. They have not, and I think that it's fair to say that I wouldn't want the exclusion in smokers because, again, it's a decision that is made between the patient and the implanting surgeon. And a discussion is held with them that they have an increased risk, and if they are willing to proceed with the procedure because they are very bothered by their stress incontinence, they -- again, each patient has the choice of choosing a pubovaginal sling, a Burch or a midurethral sling, and if it's their choice that they want to proceed knowing that they have a higher risk, that is their decision to make.
Q. Okay. And would you allow them to make that decision even knowing that they're a current smoker -- I'm sorry.
Knowing that they are a current smoker, if that is their decision after informed consent, you'll still implant it?
A. Absolutely, because even in smokers the risks for mesh exposure have never been documented to

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be astronomically high. We are not talking about a 50 percent erosion rate. We are not talking about even a 20 percent erosion rate. It's higher than the published 2 to 3 percent rate of exposure.
Q. Okay. On the two surgeries where you were the original implanting surgeon and there were later complications that you also addressed yourself, did you implant the sling in accordance with the instructions for use that Ethicon produces?
A. I did. And, you know, as a teaching physician, when I am training someone, I don't know if when I am asking a trainee to, you know, pull up on the sling with the plastic sheaths attached, if it was slightly tighter than I might have placed it. You know, I don't know what the variables are. But, yes, you know, I've placed it according to the instructions for use, both -- placed it according to the technique in which I was taught how to do it and then of course following the general guidelines provided.
Q. Okay. So yeah, in addition to the training you received in Europe, you have consulted the IFU prior to the first time you implanted a Gynecare, Ethicon, Johnson & Johnson device?
A. You know, I really and truly cannot tell

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you if I -- you know, the thing comes in the box, and looking through this, I don't know if I can recall back in 2003, of whenever it was, 2004, looking at it. I'm familiar with what it is.
Q. Okay.
A. I would never rely on a piece of paper in a box provided by a company to teach me as the implanting surgeon how to do this. Maybe that is arrogance, but I feel like it's my responsibility to not rely on something that is provided by a company to do a surgery.
Q. Okay. Do you not take into account the fact that, you know, Dr. Ulmsten and others who have been involved with Ethicon might have had -- may have had a role where their knowledge might have been transferred to Ethicon in the production of the IFU?
A. They absolutely I hope would have done that. But I would hope that I would go to the medical literature as the prime resource and understand from that medical literature what this is. In the paradigm of traditional medical education one relies on textbooks and people that are training you in your training program and published medical articles that are not implements by industry to tell you how to do

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something. Going to workshops and meetings, and these are the places to learn surgery, not learning them from a company document. I am never going to rely on a company to teach me how to do a procedure.
Q. Okay. Would you ever rely on a sales rep to teach you the procedure?
A. I would hope that my publication in 2009 would speak to that point.
Q. Well --
A. A thousand percent, no. And I think that it's absolutely not the role of a sales representative to teach anyone how to do anything.
I will -- I will make the point that if a company clearly knows that the specific steps of a procedure are X, and they want to try to improve the reproducibility of the results in any individual's hands, I think it's very reasonable to have clearly outlined steps in the IFU that should be followed. And I think that when reading the IFU, Ethicon is very clear about the necessary steps that need to be followed to achieve the outcomes that the original implant has achieved.
Q. Okay. Does your surgical approach to a retropubic sling placement vary at all from Ethicon's

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IFU?
A. It really doesn't. And I think there are a couple of very, very critical steps in there that -- absolutely no deviance is acceptable because otherwise the results may not be what you would expect them to be.
Q. I'm sorry. Your -- your statement -- just repeat that for me because I didn't quite catch that. No deviance from what now?
A. I said my de- -- I don't deviate in my surgical approach, and I think that there are some very specific steps in -- that are detailed in the IFU that cannot be deviated from or else a different result would be achieved.
Q. Okay. Would the tensioning of the sling be one of those steps?
A. The tensioning is one of the critical, critical steps. And when you remove the plastic sheaths, and if you try to tension it after the plastic sheaths are removed, very different results can be achieved.
Q. Okay. Is that what happened on the two where the tension was, as you've described, too tight in your two patients that you later repaired?

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A. No, I think in those circumstances we did the techniques like we always do, and for whatever reason in those two patients, I don't -- I don't know if I pulled the sling tighter than I thought I did or if I -- I cannot tell you exactly why. We're working with trainees. Again, I don't know if the person working with me pulled it tighter than not. But I have done them often enough and in the same way that there shouldn't be a variance. But again, I can't tell you exactly why in those two cases out of 500 of mine that they were too tight for the patients to individually void.
Q. Just so I'm clear on the record, or the record is clear, are you blaming your -- the surgeon you were training?
A. No, I'm saying that I don't know. I can't tell you because every surgery that I do is with a trainee. I can't tell you if there was something different about those two cases. I just -- I cannot tell you.
Q. That is fair. That is fair.
Have you ever perforated an organ during the placement of a retropubic sling?
A. I have certainly perforated the bladder.

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Q. Okay. How many times has that happened to the best of your recollection?
A. You know, I think that my personal rates when I am personally passing the sling are very similar to the published literature, which is, you know, four -- anywhere between 3 and 6, 7 percent. I think when trainees are involved, the rate can be higher, and this has been, again, documented in the medical evidence. But I would say overall, probably about a 3 percent rate.
Q. Okay. You can't put a specific number to it?
A. Look, I mean, because I haven't published on a cohort of my patients, I can't tell you a specific number. But from my recollection of patients in the operating room, I would venture to bet it's, as I said, originally around 3 to 8 percent.
Q. Okay.
A. I will say this, that it doesn't -- it didn't appear to deviate from the published evidence that has existed from many trials.
Q. So you would accept that is -- bladder organ specific perforations, that is well known within the literature?

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A. Absolutely well known, and not a significant issue as long as it's recognized.
Q. Okay. Would it be a more significant issue to the person whose organs were pierced?
A. Not in any respect. And if you talk to a woman who you have punctured the bladder, it's really like they've had a suprapubic catheter in place. So the clinical -- the clinical significance of intraoperative bladder perforation is a nonentity as long as it's recognized.
Q. Okay. So my understanding, again, that you were trained in Europe on this procedure -- and I'm sorry -- the retropubic sling procedure?
A. In London, correct.
Q. Okay. Who was your trainee -- trainer in London?
A. Abdul Sultan.
Q. Okay.
A. He wasn't employed by Ethicon, and he wasn't doing -- I was working with him in another capacity, and he did TVT retropubic slings, and so I learned from him how to place them.
Q. Thank you, Doctor.
One thing I forgot to ask you earlier.

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When you were in -- I read from your CV you were in Africa recently for a period of time on sabbatical?
A. Correct.
Q. Okay. Did -- did your sabbatical, did that involve any teaching of mesh procedure, retropubic mesh, anything along those lines?
A. No. I did surgery there. I can't -- I think we may have placed a retropubic sling, but it wasn't -- it was part of another prolapse repair. So I wasn't -- I wasn't sponsored to go to Africa by a company to teach. I have a joint appointment at the University of Cape Town, so I went on my own accord.
Q. Okay. Has there ever been a situation where you as a clinical doctor, whether it be your placement of a mesh or someone else's -- again, limiting this to SUI -- has there ever been a time where you have felt like the mesh itself, even if perfectly placed, caused -- had a complication arise?
A. Can I clarify, specifically, because of the property of the mesh; is that what you are asking me?
Q. Really I'm -- I don't have a, I mean, secret or a hidden agenda in terms of questions. It's just very general. It's just the best way I knew how to ask it, so --

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A. I don't -- I don't under- -- I don't really understand what you are asking me.
Q. Okay. You have pointed out specifically, a couple of times where you thought the mesh might have been overtensioned in patients that you operated on, correct?
A. Correct.
Q. Okay. And you have also referenced a larger body of patients that, whether it was your placement or not, you have treated for some type of mesh complication?
A. Correct.
Q. Okay. What I'm asking you is, have you ever made a determination as the clinical doctor that you look at a mesh or a patient, you determine that it was properly placed, but there is still a complication? Has that situation ever occurred in your clinical practice?
A. Yes.
Q. Okay. Do you -- in that situation, do you attribute the complication to the mesh itself, the mesh properties? That is what I'm asking you to explain.
A. Yes. So the best analogy that I can make

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to you probably is if you are at a picnic and everybody eats the potato salad, and 1 percent of a hundred gets sick, is the issue with the potato salad, or does that person have something else going on that made them sick? If you go to a picnic and everyone eats potato salad, and a hundred -- 99 of a hundred people get sick, you assume there is something wrong with the potato salad.
Q. Okay.
A. So the analogy that I would make of the patients that I have put in with mesh is that it seems that they all get the potato salad, and one out of a hundred or two out of a hundred may get sick.
So I cannot -- in having the same device that has the same properties implanted in patients, the variable seems to be the patient and their local host response. It doesn't seem that there is any variability in the material or in the product. There is certainly a variability in the technique in which was placed, and so that can be -- that can be an interaction in this tri-fold relationship between the mesh, the patient and the physician.
Q. Okay. There can be variability in the way it was placed?

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A. For sure.
Q. Okay. This isn't -- at this point in time this isn't a standardized procedure?
A. One would hope it would be, but this is, unfortunately, a reality where people, even though people are encouraged to standardize procedure and learn to do it with specific steps, there is still variability. And in watching enumerable people perform live surgeries, one sees variability in technique. And I think variability in technique and where someone is on their learning curve very much can have an influence on the outcome for any particular patient.
Q. Okay. Does Ethicon have sales representatives?
A. Yes, for sure.
Q. Okay. And these -- in my review of documents, it appears to me that sales representatives have marketed these products, not just to urogynecologists, but also urologists and OB/GYNs.
Is that consistent with your understanding of the medical industry?
A. Yes. But I will tell you that in the -- in the -- as an OB/GYN professor and as a urology

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professor, it is a requirement for residents from both subspecialties to be able to do midurethral slings upon graduation of residency without subspecialty training. So I think it's fair to say that both specialities have endorsed generalists being able to offer this procedure as opposed to specialists.

Q. Okay. So where does all of the variability come in if all surgeons are trying to do this, and to your knowledge in the industry, you know, all of these disciplines essentially are given the same information, where does the -- I'm just curious why -- where you think the variability comes from?

A. You know, I just -- if you take ten people driving down the highway, they are supposed to follow the rules, they are supposed to drive at the right speed. Some people speed, some people don't follow the rules, accidents happen. Is it that the car is defective, or is it the drivers? I can't tell you why individual physicians don't do things or decide to do things their way or they don't follow the IFUs. I -- I don't know why. But they're -- despite the fact that the procedure in the majority of people's hands is consistent, there is still variability in surgical practice.

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Q. Is it your opinion that the retropubic TVT Gynecare sling is the most studied medical device?

A. It's not only my opinion, it's evident in all the published literature.

Q. Okay. How long has that been true?

A. I would say that it's been true since about 2003 or '4 I would say.

Q. Okay. Did I read correctly in your report, the statement that erosions are a known complication of TVT surgeries?

A. Absolutely.

Q. Okay. Do you believe stress urinary incontinence, specifically retropubic mesh complications or adverse events are underreported?

A. In what respect? Underreported to the MAUDE database, underreported to who?

Q. Okay, sure, let's start with MAUDE database. Do you believe they are underreported?

A. Sure, to the MAUDE database, I think so, and I think the FDA believes so as well, which is certainly why they changed their modifications for vaginal mesh --

Q. Okay.

A. -- for prolapse repair.

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To the extent that they are underreported in clinical studies, no, I think that these are circumstances where you have very rigorous protocols, where you have patients that are under a microscope that are seen at much more frequent intervals than they would be seen otherwise. And I think in those settings, the -- the findings are very accurately reported.

Q. Okay. I'm sorry. Do you believe in -- well, let me just ask you it this way. I have read in several -- several medical literature sources that continued follow-up with patients is difficult, and for most randomized clinical trials there is a -- either a general or very significant loss of the cohort of patients over time.

Do you agree with that?

A. There can be, but I think interestingly in the TVT literature, we've got several examples of amazing follow-up, specifically in the Nilsson study after 17 years, I mean, a very high follow-up rate of the original cohort. In the TOMUS trial, I think their follow-up was remarkably good.

So, you know, yes, while there's a general statement that can be made, I think that there are

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certain circumstances where follow-up was actually remarkably good.

Q. And Nilsson, 17-year study, that was -- if I understand correctly, wasn't there only something like 46 out of the original 90 patients that were actually able to be visited to be viewed in the office?

A. That is correct. But if you look at the number of patients that had died in the meantime -- you know, like it was a significant amount of time that had gone by. So I don't even -- I don't recall how many were even able to be contacted because they were still alive. But the point was that they still were able to report on a significant percentage of people.

And in the Scandinavian countries where their medical system facilitates the long-term follow-up. There, in Austria, from the Austrian registry you've got very, very good long-term follow-up.

So I would say certainly in the United States where people move around a lot, it's not as easy to capture data, but from the Scandinavian countries and Austria, we've got really good, robust

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long-term follow-up with not a high lost-to-follow-up rate.
Q. Okay. So for the doctors to only be able to physically see 51 percent of the original cohort, that is, in your mind -- and I'm asking you -- is that a sufficient follow-up?
A. For 17 years, certainly, in patients we know because they are able to capture in those Scandinavian countries if a patient is seen elsewhere for a problem. They have it all available on national databases. Even if they were not able to specifically contact them at 17 years, they were able to evaluate if they had been seen for complications. And so I don't think it's some great conspiracy that these complications are being hidden from people trying to do research on this subject.
Q. Sure. And you know I did not call it a conspiracy, right? I didn't use that in my question, did I?
A. No, but I'm saying that I be- -- you know, it seems that some people believe that it's a hidden -- you know, you posed the question initially, don't I believe that there is a major issue with follow-up, that this issue was underreported.

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Q. Well, no, I said that I've read that in several sources, and I asked you what your opinion was of it.
A. Well, I think I've provided my opinion.
Q. Yeah, it wasn't an accusation. It was a question. It was a fair question, Doctor.
Okay. So in -- also in the Nilsson study, I believe a hundred percent of the women that did return for the 17-year cohort refused to submit to urodynamics; is that your understanding?
MR. ROSENBLATT: Do you want to put the study in front of her?
MR. TEAGUE: Well, I mean, she's -- she quoted it to me, so I'm just asking what her recollection is.
THE WITNESS: I certainly don't recall on the top -- off the top of my head what percent of them wanted to have urodynamics, and urodynamics would not be used in any respect as the standard for an outcome. If you look at all the pelvic floor disorders network outcomes, urodynamics is off the table completely for both preoperative evaluation and

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post-operative evaluation.
BY MR. TEAGUE:
Q. It's off the table in what regard?
A. It's not considered to be a recommended preoperative evaluation or a post-operative outcome measures. We're using patient-centered outcomes now that relate to symptoms, and that is what matters to patients, not what you find in the urodynamic study.
Q. Okay. So why would Nilsson even -- why would those researchers involved in that study, why would they even ask for it then?
A. Well, I think that it's fair that these patients originally, you know, the historical standard was to use urodynamics. If you look at the Hilton-Ward study, for example, they subjected all these women to urodynamic software that was used at that point as a metric of success. And I think Nilsson is maybe just reporting the fact that they would have been willing to offer this as an outcome measure, but, you know, are potentially using more patients than an outcome for that study now.
Q. Do you know any of the researchers involved in the Nilsson study?
A. Not personally, no.

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Q. Okay. And you are aware that Nilsson, in the 17-year study, disclosed a conflict of interest for work he has done with Ethicon, correct?
A. Sure. And I think if he was the only paper who was out there with any long-term outcomes, I would question the efficacy. But as his results are very similar to other longer-term outcome studies, no one else has 17-year outcomes, but certainly we have eight- and 10-year outcomes that are very, very similar.
Q. Okay.
A. So I don't -- on the basis of the numbers being similar, I don't discredit or disqualify his publication.
Q. Do you -- was he -- I'm sorry, was -- there are no other 17-year studies, correct?
A. Correct.
Q. Okay. How many randomized control trials -- or how many other -- how many others have gone more than five years to -- that you are aware of?
A. Gosh, probably five or six trial.
Q. Can you recall any names as we sit here today?
A. You know, gosh, right off the top of my

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head, I can't tell you the authors, but I -- if I -- if you needed me to provide you the studies, I certainly could.

Q. Okay.

MR. TEAGUE: I'm going to make that request, Counsel, any --

MR. ROSENBLATT: What is your request?

MR. TEAGUE: -- post five-year studies --

THE WITNESS: Paul Tomasino's Austrian study is certainly one of them, the --

BY MR. TEAGUE:

Q. Let me maybe short-circuit this a little bit, Doctor. Would these be studies that would be involved in your -- or be included in your reliance list?

A. All of them.

Q. Okay. Would you agree that the majority of the studies on retropubic slings have follow-ups that are less than five years?

A. Yes.

Q. Less than one year?

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A. Not the majority.

Q. Okay. Would you agree that to one extent or another all randomized control trials have some attrition of the original cohort that was -- that was part of the investigation?

A. Sure.

Q. Okay. And whether there is death or not able to find them or other reason, I mean, it does make it -- say for instance the 17-year study, I mean, even through it's perfectly legitimate, you can't interview or, you know, inspect someone who has -- who has passed away, but that still change the available data for the researchers, does it not?

MR. ROSENBLATT: Object to form.

THE WITNESS: Sure, it does. But I think it's reasonable in medicine to make the very best effort at scientific investigation reporting, and the very best effort has been made in this regard with midurethral slings.

BY MR. TEAGUE:

Q. Okay. Can you do a randomized control trial designed specifically to test for an adverse events or a contraindication?

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A. I think because adverse events are typically rare events, it's usually not viable to do a prospective randomized trial just to look for adverse events, so that is not the typical study design that is used for that. This is where large population-based studies, retrospective series, are a much better study design to try to look for events that are more rare.

Q. And I meant -- and I should have been a little more clear, Doctor. Thank you for your response though.

In terms of -- are you aware of any ethical medicolegal reasons that a study can't be designed to prove an adverse event?

MR. ROSENBLATT: Object to form.

THE WITNESS: I think that if you have a hypothesis that something is highly associated with an adverse event, that there would be ethical concerns behind designing specific to look for that. But I think that we are all aware that paying attention to potential adverse events is something that is routinely included in any well designed trial.

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BY MR. TEAGUE:

Q. Okay. In terms of erosion or extrusion, any of those things, is it possible for it to be asymptomatic for a woman but still have a negative consequence in terms of male dyspareunia or his dyspareunia?

A. Yes.

Q. Okay. Doctor, in a very general sense, what is the purpose of a nerve in the human body?

A. It's got two purposes: To provide sensory function and motor function.

Q. Okay. Where are they located?

A. Throughout the body.

Q. Okay. Are they in the pelvic region?

A. Sure.

Q. Do organs such as bladders, do those -- are there nerves located there?

A. Sure.

Q. Okay. In the urethra?

A. Sure.

Q. In the sphincter? Not necessarily -- well --

A. The nerve has to supply the urethra sphincter for it to work.

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Q. Okay. In the vagina?
A. Yes.
Q. Okay. Is it a fair statement to say that nerves relay messages of pain to -- throughout their system, ultimately to the brain?
A. Sensory nerves, that is the function of sensory nerves, yes.
Q. Sensory nerves. What other type of nerves would there be?
A. Motor nerves.
Q. And what are those -- what is their purpose?
A. To innervate the muscles to perform functions.
Q. Okay. Do they have any type of pain response involved?
A. I -- I don't think a motor -- most nerves have both components, so most nerves would be able to perform both functions.
Q. Sure. In terms of -- Doctor, you -- well, strike that. I will get back to that later.
Does the -- would you consider the organs within the female pelvic area to be close to one another?

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A. Sure.
Q. Okay. So the -- myself, the jury, anyone else who looks at this would understand, typically what type of area as someone who's performed pelvic surgeries and is familiar with the area, give us an idea within that -- within that physical location of the body, bladder, urethra, vagina, what type of space are you working in within there?
MR. ROSENBLATT: Object to form.
THE WITNESS: I -- yeah, I don't exactly know what you are asking. Are you asking like what is the distance you have for placement of a sling? What -- are you -- I mean --
BY MR. TEAGUE:
Q. Let's start there. What is the distance you have for the placement of a sling?
A. So you have about three -- a three-centimeter window from the lateral boarder of the bladder to the iliac vessels for safe placement of the sling on either side. So certainly we are talking about a relatively narrow space, and it doesn't matter if you are placing sutures there, autologous fascia or mesh, one is working in relatively close quarters.

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Q. Okay. Does a woman's -- does the relationship of those organs -- or strike that.
Does the architectural anatomy of a woman in that area, does it change as she ages?
A. It can. Certainly with a woman developing any type of prolapse, the anatomy, the relationships can change significantly. With post menopausal estrogen changes, the vaginal -- vaginal architecture can change as well.
Q. Okay. Have you ever been trained in any way in the assessment or understanding of -- well, strike that. Let me ask it a better way.
Do you have any biomaterials training?
A. Well, that was one of the things that was limiting me initially from -- from starting to implant mesh. So because I didn't have any understanding of material science in 2004, I took it upon myself to learn something about the material science, enough that I felt that I had a general understanding of mesh properties, biomechanical properties, to reasonably counsel my patients about the safety of the implant before proceeding.
Q. Okay. And what sources did you use to -- to develop your understanding?

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A. So initially, I relied on the data that had been gathered regarding hernia mesh. So despite the fact that it was different in terms of mesh load and it was different in terms of where it was placed in the body, the properties of the polypropylene mesh and how it had been evaluated gave me some understanding of the properties that I would seek in a suburethral mesh.
Q. Okay.
A. And I think that the other thing that I would have relied on was the Ahmed paper, which I think was published in about '98. But I definitely had an awareness -- or studied the different classification of mesh types. So I would say that, yeah, mesh -- it was information gleaned from that paper that I found very informational and then information from the hernia literature.
Q. Okay. And as a doctor, you have never been asked or called upon to perform any type of tensile or material test for polypropylene mesh, have you?
A. No.
Q. Okay. For any other type of synthetic device -- or synthetic material I should say?
A. Well, when you are evaluating the Y-mesh,

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as I mentioned before, for sacrocolpopexy, you know, we certainly looked at the tensile properties.
Q. And anatomically, what is that -- what conditions is that used to treat?
A. Vaginal vault prolapse and uterine prolapse.
Q. Okay. Does that involve the same placement as a retropubic sling?
A. Not at all.
Q. Okay. And it doesn't involve the same approach as a retropubic sling?
A. Correct.
(Plaintiffs' Exhibit 4 was marked for identification.)
BY MR. TEAGUE:
Q. Okay. Doctor, I'm going to show you a few documents that we received from Ethicon during discovery. I'll show you what I've marked as Exhibit 4.
Doctor, I note for the record, you are reviewing that right now. You tell me when you've had sufficient time to review it.
A. Can you tell me when this was -- when then was published?

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Q. All I can say on the back it says 2006 Ethicon, Inc., TVT 107 trademark. It would be 169751 on the very back page.
A. Okay.
Q. Doctor, this is a -- my understanding is a literature Gynecare -- well, let's start with the front.
Do you see on the very front page, that it's branded as Gynecare TVT Tension-Free Support For Incontinence?
A. Correct.
Q. Okay. And then if you turn on the inside, the product on the left-hand side, which is Bates number FMESH 169749, it says Gynecare TVT, correct?
A. Correct.
Q. Okay. And that is one of the products that Ethicon has asked you to opine upon for this litigation, correct?
A. Correct.
Q. And do you see, Doctor, the seven years of proven clinical efficacy data in the middle there?
A. Correct.
Q. Okay. 97 percent overall success rate, do you see that?

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A. Correct.
Q. Is that consistent with your clinical results?
A. So again, it depends on what you define as success. So we know from numerous trials that success is defined in many different ways.
Q. Okay.
A. So how would you define success?
Q. Well, Doctor, I'm asking -- well, okay, let's use these two. 81 percent cured, 16 percent improved.
A. Right. So in -- for a woman who is improved, she may consider her procedure to be successful. So it, again, depends on if a woman is requesting that she be dry at all times, every time, that she be dry most of the time, or she be improved. So when you ask people subjectively, were you satisfied or were you improved, it may certainly be that, you know, 97 percent give an affirmative to that answer and 3 percent say, no, I am not -- I'm not a success, the operation did not help me.
Q. Okay. If I'm mistaken, I believe either from your report or your testimony that you had previously said your success rate you felt was in the

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80 to 85 percent range?
A. So this is asking women if they are dry.
Q. Okay.
A. So being dry is different than someone's perception of success. So I quote dry rates, subjective dry rates of 80 to 85 percent. In terms of women who are overall improved, I would say that 95 to 98 percent is probably pretty accurate. There is certainly a consistent failure rate, particularly amongst patients who have severe incontinence to begin with. But again, each individual woman will give a different answer as to if they deem it to be successful.
Q. Okay. Do you believe -- are both objective and subjective determinations acceptable to you?
A. To me, all that matters is subjective outcomes, because really, it's really what the woman tells you. What objective testing we do to them really has very little relevance. It's a way that's been an accepted corroboration of a woman's testimony, but I think more and more people accept that women will tell the truth and they will let you know if they are bothered, not bothered, if they are improved, not improved. So looking at patients' in an outcome, is

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the most susceptible outcome in my opinion.
Q. Okay. The next thing on that same page, exceptional safety profile. Do you see there is three bullet points underneath that?
A. Correct.
Q. And the first one says: Low incidence of serious reported complications. The next one says: Low retention rate. And the final one says: No reported urethra erosions.
Is -- in 2006, would it be your clinical experience that there were no urethra erosions in all -- reported in all of the mesh literature?
A. I certainly know that the -- that the rate of urethra erosion has consistently been reported less than 1 percent, so it ranges between .3 to .8 percent. So I don't know when those urethra erosions occurred to collect that less than 1 percent. I -- you know, in the references that have been provided here, 1 to 11, if there were no urethra erosions, there were no urethra erosions. But certainly I don't doubt -- there are urethra erosions, and I think that a rate of less than 1 percent is an accurate rate to report.
Q. Okay. But I don't -- I don't see anything about less than 1 percent on this --

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A. Well, they provide a reference to 1 to 11. So I would imagine that in the papers that they reference on the back, that they were not a reported -- there weren't any reported urethra erosions in those 11 papers. Now, were they leaving out information that was available? I don't know.
Q. Okay.
A. I certainly can tell you in the Shimerf [phonetic] review, from 2014, that urethra erosions in all of the meta analyses that have been done come in at about .3 percent.
Q. Okay. But again, I'm not asking about any other studies or anything else. I'm asking about no reported urethra erosions -- and I'm asking you this specifically: In 2006, were you aware, did you believe that a complication associated with mesh was urethra erosion?
A. Certainly, that is a possibility. And had I observed one at that point? No. Was I aware of it being able to be seen? Sure. And I think anybody who has done any pubovaginal incontinence work knows that urethra injury is a known and accepted complication of the procedure.
Q. Okay. When did that become known?

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A. It's been known ever since people have been doing incontinence surgery. If you are dissecting around the urethra, urethra injuries occur. There is a known and accepted rate of urethra injury with any kind of pubovaginal sling and even with Burch.
Q. Okay. If you look at -- and I will give you a second to check this for yourself, but as I was -- I circled the footnotes 1 through 11, and the dates of these studies were 1999, 1998, 1998, 1999, '99, '99, '99, '95, '95, 2000 and 2003.
Were there any -- by 2006, do you believe there were any additional clinical trials that could have been -- or I would say not even limited to clinical trials. Were there other studies that were available between the years 2003 and 2006 that Ethicon would have had access to?
A. For sure.
Q. Okay. And I'm guessing that you don't -- or do you have any idea why Ethicon would not have quoted more up-to-date literature in the design of this piece?
A. Again, as --
MR. ROSENBLATT: Object to form.
THE WITNESS: -- someone who doesn't

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work for Ethicon, I have no idea what decisions they made to produce this document.
BY MR. TEAGUE:
Q. Okay. If -- would you consider it less than honest or in any way problematic if Gynecare had individual reports of urethra erosions that may not have been -- that may not have come through the medical literature, would they have a duty to report this? Would you consider that something that would be their responsibility to tell the circumstance?
MR. ROSENBLATT: Object to form.
THE WITNESS: I mean, yeah, if you are asking me if a company hid negative information that they received, I do think they have a duty to report that, for sure.
(Plaintiffs' Exhibit 5 was marked for identification.)
BY MR. TEAGUE:
Q. Let me show you what I've marked as Exhibit 5. This document, again, was produced by Ethicon, and this says issue report TVT retropubic 1999 through 2000 Open Date 1 January 1999 and 31 December 2000.

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Doctor, while you are reviewing that, I'm just going to ask you, do you recognize this? Have you seen it before?
A. No, I have not.
Q. Okay. Do you see -- tell me when you are ready to proceed.
A. Sure, go ahead.
Q. Okay. Do you see the entered date, top left-hand corner, says July 6th, 1999?
A. Correct.
Q. And the event date was June 3rd, 1999?
A. Uh-huh (affirmative).
Q. Okay. And the Ethicon alert date was June 28th, 1999?
A. Yes.
Q. And the event description says: Received call from sales rep and was reported that there was possible TVT erosion. The surgeon had to cut the tape. Unknown lot number.
Did I read that correctly?
A. Correct.
Q. Okay. And then do you see if you go down, it says: Further follow-up completed by the medical directory with the surgeon. It was reported the

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procedure was uneventful on April 26th. Patient was a 32-year-old obese female with a prior history of hysterectomy. The patient was diagnosed with hypermobile urethra.
And then postop: The patient had a Foley catheter in place for one week. June 3rd, five weeks postop, the patient arrived at the ER with severe dysuria. A catheter could not be passed. Cystoscopy revealed that the TVT tape eroded to the posterior urethra wall in the prominent -- or prom, I think it should prominale region portion. The patient underwent surgery to excise the TVT and repair the urethra wall. Ten days postop via emergency surgery patient reports the leakage to be worse than prior to the original surgery.
So can we at least agree that the adverse event or issue that was reported to Ethicon was in fact a urethra erosion?
A. Or -- certainly, it could have been a urethra erosion. It's -- or it could have been placement of the tape in the urethra. So this is a very short postoperative time. So in looking at this, I would have attributed this to placement of the mesh through the urethra at the time of surgery --

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Q. That would just be your --
A. -- more likely --
MR. ROSENBLATT: Let her finish the answer.
MR. TEAGUE: I'm sorry.
THE WITNESS: -- more likely than not that, you know, this is in a very, very short postoperative time that the patient has this complaint. So certainly it could be a urethra erosion, but in looking at this, I would really say that because it's such a short time interval, that I would have considered that the surgeon have placed this through the urethra at the time of the procedure.
BY MR. TEAGUE:
Q. Without any evidence, you can just divine that?
A. I said to you that the post surgical interval of five weeks is the information that would make me postulate that it had been placed through the urethra at the time of surgery.
Q. So in your opinion, any urethra erosion within what period of -- within a five- or six-week

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window would be surgeon error?
MR. ROSENBLATT: Object to form. You asked her specifically about this event. You are asking her about -- are you now asking just generally?
MR. TEAGUE: Was my question that difficult?
MR. ROSENBLATT: I'm just asking --
MR. TEAGUE: No, no, if you don't under -- if you don't understand, that's -- please let --
BY MR. TEAGUE:
Q. If you need me to rephrase it, Dr. Matthews, I'm happy to do that.
A. So one of the requirements of the procedure is that one has to do cystoscopy of both the bladder and the urethra at the time of surgery because it's well known that you can place this mesh through the urethra.
So I would opine to you that if a patient is diagnosed with a urethra -- with urethra mesh within a relatively short time period, I'm not going to limit myself to one week, six weeks, eight weeks, but a relatively short period of time after surgery, I

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would be concerned that the surgeon had placed it through the urethra at the time of the original surgery.
Q. Okay.
A. So based on what -- just what you provided here, I would not automatically assume that it was product error. I would say I would need to look at the cystoscopy reports, the urethra -- if ureteroscopy was performed, exactly what were the details of the procedure to make that determination.
Q. That's where I was going to go and then -- and I understand your response. Your first response was, well, this was surgeon error, and I was just curious as to how you got there.
A. No, I said this is -- this is within the two things in the differential diagnosis. I didn't immediately say it was surgeon error. I said the two things that it could be is urethra erosion or surgeon error.
Q. Fair enough.
A. So I listed urethra erosion first before I said surgeon error.
Q. It could be -- could be either one --
A. Could be either one.

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Q. -- right? And I'm not asking you to review this for the purpose of making a decision. I'm showing this to you to show that there were reports of urethra erosion to Gynecare or Ethicon. I'm also showing you Exhibit 4 that says no reported urethra erosions.
A. But --
Q. Well, no, let me -- I haven't asked my question yet.
I have a concern when a company has information like this but still feels comfortable putting this out even if they do have some medical literature to base that upon.
MR. ROSENBLATT: Object to narrative. Do you have a question?
MR. TEAGUE: Yeah, I'm getting to my question.
MR. ROSENBLATT: Okay.
MR. TEAGUE: But you interrupted it, so I'll ask it again.
BY MR. TEAGUE:
Q. Doctor, I didn't mean to raise my voice. That's at your counsel.
So I'm going to ask you simply: You -- we

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have here a report of urethra erosion that came to them in January 28 of 1999. Okay? We also have a 2006 --
A. Can I just clarify that it says on the thing possible erosion. It doesn't say -- it doesn't say actual erosion, It says possible erosion. So I just want you to make sure you phrase that to reflect that correctly in the record, that you don't have a case of urethra erosion, you've got possible erosion.
Q. Okay. I'm reading here again: Cystoscopy revealed that the TV tape -- TVT tape eroded to the posterior urethra wall in the prominent portion.
Now, that sounds like a finding to me, Doctor. Does it not to you?
A. It doesn't explain -- it doesn't tell me whether or not that was placed that way at the time of the original surgery or if something changed over the five weeks following implantation.
Q. But that is not what I asked you. I asked -- you said there was no diagnosis. I'm reading to you that a cystoscopy, which is what you told me you do to check the bladder and urethra, revealed that -- revealed that the TVT tape eroded to the posterior urethra.

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A. On five weeks after surgery, not at the time of the original procedure. So at the time of the original procedure, that's when you would want to have evaluation of the cystoscopy and the ureteroscopy to ensure that the surgeon actually looked at the urethra upon withdraw of the cystoscope.
Q. Okay. Fair enough. But since we don't have that, but we do have a cystoscopy five weeks later documenting urethra erosion, I point that out to you not because, again --
A. It's not documenting urethra erosion, it's documenting presence of mesh in the urethra, but that does not mean there was a urethra erosion. It means that there is mesh --
Q. Okay.
A. -- in the urethra.
Q. Okay.
A. It could have arisen from two different sources.
Q. Okay. That is fine. So we -- what I'm saying is -- okay, that is fine. All right. So that's the way you parse it is that -- or that's -- excuse me, I don't want to be negative. That's --
MR. ROSENBLATT: Argumentative.

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MR. TEAGUE: Yeah, so I struck that.
BY MR. TEAGUE:
Q. So your interpretation of that is it could have been -- it could have been one of those two scenarios, and you are not comfortable saying which one it is at this time?
A. That is correct.
Q. Okay.
A. And I don't think it's fair to conclude that this was definitive evidence of urethra erosion that the company hid from -- from anybody publicly. I think what they are reporting and they are referencing on this material are 11 or 10 -- 11 references where they didn't have reported urethra erosions. And on the basis of that, you know, certainly it seems that if someone wants to check and see if there were any urethra erosions in those 11 publications, there may be, but if they claim that there are not, they probably are indeed correct that there were not from those 11 publications.
Q. Okay. Would you agree with me that the reporter -- or whoever it is it that authored this sentence said the TV tape eroded? They used the term eroded, not me. Do you understand that?

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MR. ROSENBLATT: Object to form.
THE WITNESS: That is correct, and this is the implanting surgeon. And if I were the implanting surgeon, I might have used similar language --
BY MR. TEAGUE:
Q. Okay.
A. -- if I didn't want to be held responsible for putting it there in the first place.
Q. So is it your medical experience that surgeons lie to cover themselves?
A. You know something, I think that people want to hope for the best when they are doing what they're doing, and if they find -- it's much -- who -- I would like to look at the original cystoscopy report to provide -- render an opinion.
Q. I'm sorry, are you done with your answer?
A. Yes.
MR. TEAGUE: We got to go, change the tape.
THE VIDEOGRAPHER: This is the end of videotape No. 2 in the deposition of Catherine Matthews, MD. The time is 1:01 p.m. We are off the record.

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(Recess taken.)
THE VIDEOGRAPHER: We are back on the record. The time is 1:52 p.m. This is the beginning of tape No. -- videotape No. 3 in the deposition of Catherine Matthews, MD.
BY MR. TEAGUE:
Q. Doctor, thank you, back on the record.
And just to follow up on Exhibit 5, the issue report, do you recall that before the break that we looked at?
A. Yes.
Q. Okay. And just a few things I want to clear up, and I think we can do this pretty quick. At this point neither one of us has seen the operative report, so we can't make a determination based on this alone whether it was either of the two scenarios, a true erosion or doctor error, correct?
A. Correct.
Q. Okay. And we don't have any -- I mean, is it fair to say you are not actually testifying to any reasonable degree of certainty that this doctor lied to Ethicon, are you?
A. No, but I don't -- I think that it's difficult for him to have an opinion as to whether or

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not it was erosion versus placement at the time. I mean, he uses that term, but I think that it's in some respects potentially semantics on his part too, that if you see mesh in the urethra, to term it a erosion, it doesn't provide causation as to how it got there.
Q. Okay. The term alone doesn't in your opinion supply causation?
A. That is correct.
Q. Okay. If you would, Doctor, just turn to the next page, the backside of that first page, it's 466. And the only other thing I would point out is that do you see there is a series of four questions there?
A. Correct.
Q. And the first one deals with death, so obviously we know that one is -- the response is a no.
But looking at the second one: Does the reported information reasonably suggest that one of the companies' medical devices may have caused or contributed to a serious injury as defined as life threatening injury, permanent impairment of a body function or permanent damage to a body structure, and their response was yes, correct?
A. Correct.

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Q. And the next question, No. 3, it says: Has a person qualified to make a medical judgment reached a conclusion that the device did not cause or contribute to death or serious injury or that the malfunction were not likely to cause or contribute to a death or serious injury if it were to recur, and their answer was no, correct?
A. Correct.
Q. Okay.
(Plaintiffs' Exhibit 6 was marked for identification.)
BY MR. TEAGUE:
Q. Doctor, I will show you what I have marked as -- as Exhibit 6, and Counsel.
Doctor, while you're reviewing that, did you just -- the first page of the document is entitled 2002 U.S. Marketing Plan for Gynecare TVT Tension-Free Support for Incontinence, correct?
A. Correct.
Q. Doctor, as you are looking at this, when you feel comfortable, would you let me know if this is a document you've seen before in your review of Ethicon materials?
A. I have not.

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Q. Okay. And when you are ready, I have some questions on the third page, which is the Eth.mesh 9306901.
And under the heading Competition, second paragraph, it says: Already in 2001, talk among urologists has shifted from why surgeons shouldn't use TVT (for example, due to concerns about urethra erosion) to how they can take TVT better.
And I bring this up just to raise the issue again, this is a second time we have seen a reference to urethra erosion in Gynecare Ethicon materials.
As a doctor sitting here today, does that give you any reason to be concerned about the opinions you've proffered or whether urethra erosions were documented or known to the company at this time?
MR. ROSENBLATT: Object to form.
THE WITNESS: The specific document, the way that I read this from my English, is that they weren't talking about their concerns but the urologists' concerns about urethra erosion. And certainly, as a physician, at that time it was a rational concern knowing that you are operating around the urethra, that you've got a

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permanent synthetic implant, that there would have been a rational concern.
So it doesn't change anything about my opinions. I think that it was the premise for how the procedure was being done. I had a concern about the permanent material in many different respects. And so I think that this is a reflection of concern on the part of the surgeons, not concern on the part of just the company.
BY MR. TEAGUE:
Q. Okay. And -- but as we discussed before to be fair, you've said it oftentimes, surgeons are in the better position to understand the risk and benefits of a procedure, and by risk I would include urethra erosion?
A. That is correct. And it seemed what they were saying is they're moving away from an understanding that this risk before, that there was a perception that it might be high, actually in reality was not high and actually had not been recognized in that published trials to that point.
So I think that it's fair that it was a clinical concern based on knowledge of the surgical

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anatomy and the procedure that was being done, and that I think the surgeons just like myself moved away from the theoretical concern to seeing evidence that there wasn't a high rate of urethra erosion or even a rate that was more than 1 percent.
Q. Okay. And just tell me if I'm wrong in my summary here: It's your interpretation of this document is that urologists are concerned, but there is no evidence to support that there are urethra erosions happening with TVT Gynecare procedures?
A. That is not a true statement, and that is not what I said.
Q. Okay.
A. What is evident here, and this reflects my personal situation, was that there was general concern about the use of a synthetic material in the suburethral space. But after evaluation of the device and some prospective trials, at that point the concern began to mitigate.
Q. Okay.
A. And in all the subsequent collection of data regarding TVT we have observed a very, very low rate of urethra erosion. So the concern that initially was present was indeed an unrealized

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concern.
Q. Just using your testimony, this date, September 28th, 2001, this would have been before you personally had reached that conclusion based on the medical literature?
A. That is correct.
Q. Okay.
(Plaintiffs' Exhibit 7 was marked for identification.)
BY MR. TEAGUE:
Q. And I'll mark this as 7. This is a very similar report to the one I marked in 5. I would just mark -- note again while you are reviewing that that the enter date was June 30, 2000, and the alert date was the same, correct?
A. Correct.
Q. And I apologize, Doctor, do you need another minute to review?
The only thing I would -- or again, I would point out under the investigative comments, that while a lot of this is redacted and I can't read it in full, the second sentence says: The doctor reports this patient underwent TVT in the fall of 1999. And then after symptoms and waging recurring fraction, failed

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medical therapy, she is referred to urology, quote, who performed cystoscopy and diagnosed a posterior urethra erosion with urethrovaginal fistula.
Did I read that correctly?
A. Correct.
Q. Okay. So again, in this example, there was a second doctor, a urologist, who looked at this and actually diagnosed a posterior urethra erosion.
Again, given that this was information provided to Ethicon by at least June 30th of 2000, does it concern you that later marketing pieces would tout that there was no reported urethra erosions when here we have not just one but a second doctor who reviewed a patient and the second doctor who has no conflicts, no reason to cover himself, has reported that this is a urethra erosion?
A. Certainly, it does appear that this was -- this was more likely to have been a ure- -- an erosion, and certainly there was evidence -- not even erosion but a fistula. So certainly, it appears that there was evidence and how much -- to what extent this should have been shared with marketing, you know, I can't comment on the internal documents. But, yes, it seems reasonable that they could disclose this.

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Q. Okay.
A. And this may have been reported to the MAUDE database. I don't know. It probably was.
Q. Okay. And then under the -- you see the comment that was entered July 12th, 2000, starting halfway through that, it says: While the erosion may have arisen from user error -- so they acknowledge that that is possible -- it may have been associated with mesh rejection or like the most recent symptoms have been a consequence of mesh infection.
And I'm -- again, I know you are -- well, let me just ask it this way. As a clinical physician, how would you interpret those phrases, mesh rejection and then mesh infection? You can start first with mesh rejection.
A. I don't know what is meant by the term mesh rejection. In the implantation of the more than 3 million slings that we have in there, we don't have a clinical composite of symptoms that is consistent with quote/unquote rejection. So I don't really know what to make of that term.
Q. Okay. Fair enough.
What about mesh infection?
A. Certainly, infection of a synthetic

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polypropylene material is a well known risk, and infection can lead to complications of the tissue and breakdown of the tissue surrounding the mesh. So it certainly seems that that is a plausible explanation for what happened.
Q. Okay. And what are -- what -- you said that there are -- you know, I apologize, the doctor-ese I don't do as well as you do, but -- so what are some of the -- what are some of the known -- I'll use the word attributes for now -- what are some of the known attributes for mesh infection? What do you see, how do you determine that, how do you make that clinical diagnosis?
A. How do you make the diagnosis of mesh infection, or how do you -- what are the clinical attributes of a mesh that link -- that cause infection?
Q. Okay. Well, let's start with the second part. What are the clinical attributes of mesh that cause infection?
A. So we know that the smaller the pore size of a mesh -- the mesh, the greater chance of infection. There is a very significant linear correlation between the two. And that is because the

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meshes that have very small pore size, the bacteria can get in, but the body's white blood cells to fight the infection are too big to fit into the space. And so there's a very significant -- a significantly higher rate of infection for small pore mesh. This is a higher rate of infection in mesh that is multifilament and mesh that is heavier weight as opposed to a lightweight material.

Q. And I just note earlier, it was noted as a TVT, but -- so are you saying that TVT has the small mesh size?

A. No, the small -- it has the largest pore size of all the commercially available meshes.

Q. Okay. So let me just redirect your question in terms of TVT, what would be -- how would you -- how would you -- what -- what would you associate with mesh infection in a TVT size mesh?

A. So, you know, I think that, again, there are host factors, there are surgeon factors, and there are mesh factors.

Q. If you would, break each of them down for me.

A. So the surgeon factors would be if the mesh is placed in the wrong -- if the mesh is placed in the

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wrong tissue plane, so either too close to the urethra bladder or in the urethra bladder or too close to the vagina. If the mesh -- so, yeah, I would say that those would be the main factors. If the surgeon contaminated the mesh in placement, touched it to something that was not sterile --

Q. Okay.

A. -- used a nonsterile insertion technique, didn't give perioperative antibiotics.

The patient factors would be if there was a preexisting infection in the vagina. The patient was a smoker, again, they probably have a higher risk of infection.

Q. Okay.

A. And then the mesh properties, again, because the same mesh is put in in each patient, I've told you the general mesh properties that are associated as the TVT mesh has a large pore size relatively, is monofilament mesh. It's the lowest profile for infection, but still infection exists with any foreign body.

Q. Okay. So again, since we don't know which of the three it is, if you were to look at that and rule out doctor error, knowing that it's a TVT, which

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as you describe it has a large pore mesh, what within the properties of that mesh do you consider -- or that was a bad question. Strike that.

All right. If you were to rule out the doctor error or that it was contaminated prior to implant and you are only left with the mesh itself, what are the -- what would you look at to determine -- or how would you determine whether or not the infection arose? That is a bad question.

MR. ROSENBLATT: Object to form.

BY MR. TEAGUE:

Q. Do you understand that at all? And maybe you've already covered that. It may -- let me just ask: Is there anything -- is there anything you need to add to your previous answer, because I think I'm -- I really just asked a bad question, and I think you probably already covered it. So are you good with me moving on at this point?

A. Sure.

Q. All right. Fair enough.

Doctor, we have talked about, to some extent -- you know, strike that. I'll -- I'll let you look at this first, and then we will talk about it.

(Plaintiffs' Exhibit 8 was marked for

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identification.)

BY MR. TEAGUE:

Q. I'll hand you what I've marked as Exhibit 8. This is an internal e-mail we received during discovery, and the two parties Axel Arnaud and Martin Weisberg.

Do you happen to know either of those persons?

A. I do not.

Q. Okay. And my concern or what I wanted to ask you about, as someone who is representing Ethicon at this deposition, or at least testifying on their behalf, it says -- and this is Bates number 3910175, and the last full paragraph, the e-mail at the bottom, Dear Marty, and this is an October 13th, 2002, e-mail.

This is Axel Arnaud writing: Dear Marty, I reviewed your draft report. Apart from minor corrections concerning typing errors, it is perfect for me. I just had a concern about your statement concerning potential complications/fistula and erosions. This is a problem which arises rather commonly in practice, even polypropylene, and it might be wise to be, quote, more elusive on this.

And this is, obviously, in terms of some --

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it looks to me labeling or at least something that is intended to address potential complications of fistula and erosion as shown in No. 5 above.

Now, my direct question to you is does it concern you that an Ethicon representative would recommend to another Ethicon representative to be quote/unquote elusive on something that appears to be a warning or an indication for their product?

MR. ROSENBLATT: Object to form, lack of foundation.

THE WITNESS: Well, first of all, I -- you know, when you look at the broad category of potential complications, fistula and erosions is a very broad category of things. So am I concerned if a company -- I am concerned if a company deliberately hides significant risks from patients. So to what extent being elusive is hiding this, I don't know to what extent that means. The word elusive can mean many different things.

So I don't think that I am qualified to provide direct commentary on this. I have no doubt that internal communications

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exist to try to maximize the marketing ability of a product.

BY MR. TEAGUE:

Q. Okay. Does it concern you then that a manufacturer, a device manufacturer like Ethicon might place profits over potential safety issues?

A. I think --

MR. ROSENBLATT: Objection to form.

THE WITNESS: I think that really and truly, this is another example of how studies that are conducted independent of industry are necessary to validate in a non-biased fashion if there are complications. So there is nothing elusive, hidden or any way disguised in the Level I evidence that is published.

So in my -- in my opinion, that is information that physicians rely on, not anything that comes up from marketing. So we are responsible to look at the evidence that is very transparent and very clearly collected to determine the rates. And the rest of it is all bias to some extent.

BY MR. TEAGUE:

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Q. Okay. Well, then, do I take it from your testimony that there is some level of elusiveness or bias apparent in anything that is put out by a device manufacturer?

A. Advertising --

MR. ROSENBLATT: Objection --

THE WITNESS: -- and marketing is elusive.

MR. ROSENBLATT: Object to the characterization.

BY MR. TEAGUE:

Q. Do you -- while we are on that subject, do you think it's wise for companies to advertise or market products? So that I mean --

A. Are you talking about medical companies?

Q. Well, yeah, sure.

A. Like what companies are you talking about, chocolate companies?

Q. Yeah, I'm talking about medical companies. I mean, the role of advertising, to reach, you know, consumers and influence them --

A. So -- so --

Q. -- outside the --

A. -- if you want --

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Q. --.

A. -- so the greatest revenue from television at the moment comes from pharmaceutical companies selling drugs to patients directly. Do I personally like that practice? Absolutely not. I think it's --

Q. Okay.

A. -- it's not -- it's not a great portion of medicine, but it's a reality in America. So if you want to transform the entire way that medicine is practiced here, go for it. But I mean, yeah, my personal opinion is direct-to-consumer advertising is not great.

Q. Okay. And let me ask you just one last question on No. 8. Is this one of the documents you were shown in the package that you received from Ethicon?

A. No. As I said before, I asked them specifically to show me the clinical trials and studies that they had done internally to evaluate their product.

Q. Okay. And does it concern you when you asked for documents that would give you a full and fair picture that something describes the elusiveness -- and I'm using their words, the

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elusiveness of a warning -- that doesn't bother you at all as someone who is here testifying on their behalf?

MR. ROSENBLATT: Object to form. I'm just going to point out, Counsel, what you read is not about TVT, and I will leave it at that.

MR. TEAGUE: I -- Counsel, if your representation is that they would only be elusiveness about one product and not the whole rest of their family, then, sure, I'll take that. You'll make that representation? That's all right, we can --

MR. ROSENBLATT: You can move on and ask your next question. I just want you to ask your questions --

MR. TEAGUE: That question hasn't been answered.

MR. ROSENBLATT: -- in the context of the TVT.

MR. TEAGUE: That question hasn't been answered. That is fine.

MR. ROSENBLATT: Okay.

MR. TEAGUE: That question hasn't

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been answered.

MR. ROSENBLATT: What is your question?

THE WITNESS: Can you read back the question to me, please?

THE REPORTER: I'll try --

MR. TEAGUE: I'll rephrase it. I'll rephrase it.

BY MR. TEAGUE:

Q. Doctor, granted, given that this is an e-mail between Ethicon representatives that uses the word elusive in something that they are going to use to describe rates or complications associated with fistula erosion, does the term elusive bother you at all?

A. Reading the --

MR. ROSENBLATT: Object to form, lack of foundation.

THE WITNESS: In the context of all the millions of e-mails that I am sure that you've sifted through to find the word elusive, does that concern me? No. I think that you are really searching for straws here out of millions of things that

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you must have gone through to find the one word elusive.

BY MR. TEAGUE:

Q. Okay. If that is your opinion, I'll more than happily take that. I'm fine with that testimony.

(Plaintiffs' Exhibit 9 was marked for identification.)

BY MR. TEAGUE:

Q. I'll show you what I've marked as 9.

MR. ROSENBLATT: Do you have an extra copy?

MR. TEAGUE: I do, sorry.

BY MR. TEAGUE:

Q. And this is a document that, again, is branded Gynecare Worldwide, noted as a memo, and the title is TVT phase and TVT-O Compliant Review for Laser Cut Mesh Risk Analysis?

And, Doctor, primarily, I wanted to get your opinion on the second page, the analysis page, and you just tell me when you are ready to turn there.

Doctor, what I specifically want to ask you about is, in that first paragraph, the last sentence of analysis, it says: For TVT base product number 810041B, approximately 65 percent of all complaints

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fall into the following groupings: Mesh fraying/roping, sheath damage, erosion, exposure and pain.

Doctor, do you believe that mesh fraying is a complaint that is associated with TVT Gynecare?

A. Yes.

Q. Okay. Describe for me, help me understand -- or in your clinical -- strike that.

What do you -- how do you determine mesh fraying?

A. So if one puts significant tension on the ends of the mesh when you remove the overlying the plastic sheaths, you can deform the mesh, and you can pull it into a tight bend with fraying of the edges.

Q. Okay. Is that a design defect?

MR. ROSENBLATT: Object to form, calls for a legal conclusion.

THE WITNESS: It's not a design defect because that's not how it's supposed to be used. So if you adjust the mesh with the plastic sheaths overlying it, you can't deform it, and that is how the mesh is supposed to be tensioned, with the plastic sheaths in place.

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BY MR. TEAGUE:
Q. Okay. Did -- to your knowledge, did Ethicon or Gynecare ever change the sheaths in any of their products, from the original TVT Gynecare version?
A. I'm trying to recall as the surgeon. I -- I don't know specifically. There's always been a plastic sheath that's completely covered the mesh, and you are not able to deform the mesh when you're using the sheaths that are covered. So whether or not it changed, I don't know. I know that since I've used it in 2004, 2005 to now, I have noticed the same properties of the sheath.
Q. Okay. How would you interpret sheath damage from this e-mail, just in your experience? Do you have any idea?
A. I don't know if they were defects in the external sheath that was torn in some respect or missing. I don't know what that means.
Q. Okay. What about erosion, we -- I know we've covered that a good bit today, but do you have anything -- well, strike that, we've already covered erosion, so we can move on.
What do you consider -- what is your

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understanding of the term exposure is the next bullet point?
A. Exposure specifically references mesh that's visible in the vagina.
Q. Okay. And what about -- the word pain is here, and obviously I'm not going to ask you to necessarily divine what they meant by that. But what types of pain do you see with the retropubic TVT Gynecare?
A. So certainly, and what's been again described in the literature, there have been few reports of retropubic pain, and I have seen a case of that, pain with intercourse. And really the leg and thigh pain seems to be specifically limited to the transobturator sling. So I think that to the extent that it's specifically related to TVT, I would say suprapubic pain and dyspareunia.
Q. Okay. Would you -- in another deposition I was reading, I believe it was yours, but correct me if I'm wrong, you had made a distinction between initial thigh or inner groin pain was more associated with a TOT sling, obturator sling, but that postoperative, you had seen more cases of pain in the thigh after the retropubic down the road.

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A. No. I -- if you look at the results of the TOMUS trial, I think that it's very consistent that transobturator slings are associated with thigh and groin pain, whereas retropubics don't have a significant association with thigh and groin pain. Whether or not some patient has complained of that, it's certainly possible. But in the medical literature, the peers that find groin pain is much more affiliated with transobturator than retropubic.
Q. Okay. And that is in all phases from post surgical to, you know, whatever infinite life you want to roll down the -- or strike that.
That would -- you would include in your definition, both the postoperative period and the period following that?
A. Yeah, every -- all patients have some degree of pain in the immediate postoperative period, so it's difficult to identify if that is normal pain or pathologic pain. I think that longer term pathologic pain that is experienced more than six weeks out from the procedure, again, if you are talking specifically about thigh and groin pain, it's much more commonly observed with the transobturator.
Q. Okay. Do you -- in some of the expert

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reports that have been produced in this litigation, there is mention of -- that if a -- if a chronic type of pain exists for long enough, that at points the amino acids take over and continue to send that signal, even without necessarily a -- I guess like a reaction or without an initiator of some kind for lack of a better word.
Do you have any thoughts on that as -- do you deal with, you know -- or based on what I just said, do you have any thoughts on that at this point?
A. I've never heard the theory proposed that amino acids act to --
Q. Yeah, you know what, I should have just -- I'll -- you know, I'll tell you what, I will read it directly because I thought I could wing it, but it's probably better that I just put it in front of me and read it, so I don't -- because I don't want to misrepresent anything that was said.
A. Okay.
MR. ROSENBLATT: And which expert report are you referring to?
MR. TEAGUE: That is what I'm saying, I need to just pull my notes and see.
MR. ROSENBLATT: Okay.

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BY MR. TEAGUE:
Q. Yeah, the comment that I saw -- and this was from one of the depositions you took in AMS -- was that thigh pain in retropubic slings was higher after six months. Is that an opinion you still hold?
A. It's whatever the results are from the TOMUS trial --
Q. Yeah.
A. -- so I'm very happy to pull that paper and have us look at that together. But it's whatever the longer term outcomes are from the TOMUS trial that gives us the best information comparatively of retropubic to transobturator.
Q. Yeah. And I believe that you had mentioned of the five that were reported, only one of the five was transobturator, the other four were retropubic, after the six-month period.
Does that sound familiar to you based on your reading of the --
A. I would want to review the TOMUS trial again to look specifically at the numbers to corroborate that. It's possibly true, but I would like to look at it.
Q. Okay. Doctor, you have had involvement

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in AUGS, correct?
A. Very much so, yes.
Q. The -- and if you would, define what AUGS is for the record.
A. American Urogynecology Society.
Q. Okay. And have you served as an officer or elected representative in any capacity?
A. I have. I was the vice chair and then chair of the foundation for AUGS and served on the board in that capacity.
Q. Okay. AUGS allows corporate or manufacturing or industry -- manufacturers themselves to join AUGS; is that correct?
A. I think anybody is -- anyone is able to join AUGS, correct.
Q. Okay. And were you aware that Ethicon was a member of AUGS?
A. It doesn't -- it doesn't surprise me at all. I certainly know of attorneys being members. So, yeah, that doesn't surprise me at all.
Q. Is it open to gynecologists and urologists as well?
A. Yeah. So, I mean, that's specifically who it's designed to serve.

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Q. Okay. Do you know what percentage of doctors practicing in pelvic medicine belong to AUGS? Without assuming. I'm just asking if you know.
A. I think that when you say practicing urogynecology, I don't know exactly what you mean by that. Do you mean doing the full complement of pelvic floor disorder treatment, or do you mean just placing slings?
Q. I mean, I didn't really have a specific -- I meant, you know, say roughly taking OB/GYNs, urologists, gynecologists as a whole, do you know what percentage of those practicing doctors would belong to AUGS? Have you ever seen any --
A. Well, I think that -- gosh, almost --
Q. -- data?
A. - almost a hundred percent of people who are board certified urogynecologists are members of AUGS. I'm sure it's not 100 percent because nobody is ever 100 percent, but it's a very high number.
Of generalists who do urogynecologic procedures, I cannot give you a breakdown, but I'm sure that AUGS could provide you that information if necessary.
Q. Okay. In terms of other experts in this

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litigation, have you read -- I know you've read reports, and you disclosed those in your report.
But have you actually read any medical literature from any of the other -- from any of the plaintiff-designated experts?
A. I have read medical literature from Dr. Blaivas, yes.
Q. Okay.
A. And I've lectured with him at a conf- -- at several conferences.
Q. Okay. So you all know each other?
A. For sure.
Q. Okay. Have you -- have you all ever worked together in any capacity?
A. I -- in terms of being speakers at the same conference, yes, but not to do -- not otherwise.
Q. Okay. In terms of his qualifications do you have any doubt that he is qualified to illicit his opinions on mesh, mesh properties, injuries associated with mesh?
MR. ROSENBLATT: Object to form.
THE WITNESS: I think that -- I think that Dr. Blaivas is biased, I think, but I don't -- I certainly respect his medical --

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respect his position in the field.
BY MR. TEAGUE:
Q. Okay. Biased how?
A. I think that it's interesting that, you know, Dr. Blaivas has served on some important boards within the AUA that have looked at outcomes of different incontinence procedures. He seemingly agreed with the results that they've published, and then personally he has provided different information. So to the extent that, you know, I -- to that extent it's a little bit confusing as to where his positions really come from.
Q. Do you not worry that the same could be said for you?
A. I think that I am very, very, very representative of the vast Level I medical evidence that has been published on the subject. So I don't think that I am presenting opinions that fly in the face of the best medical evidence that exists.
Q. Okay. In terms of -- obviously, you have been critical of sales reps. You have written a paper that, you know, describes some issues you have with industry.
So to put it into that category, are you

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not concerned that you'll lose some credibility on the -- on that front to have published such a paper and then to later represent industry at trial?
A. I'm not here representing Ethicon, I'm here representing TVT as the best procedure for the management of stress incontinence in women.
Q. Okay. Do you separate Ethicon and Gynecare TVT? I mean, that is the manufacturer.
A. The company -- the company produces the product, but it's the product that I'm here defending vehemently because I believe that if this product is removed as an option for the management of stress incontinence in women, the many, many, many thousands of women that I treat in my practice are going to be very much harmed by not having this as an available option to them.
Q. Would you agree with me that to the extent it's proven it's failed in an individual woman and that woman's compensated by a jury, that is not -- that doesn't clinically mean anything is going to be taken off the market, does it?
A. I think that what I'm here to do is to provide the best -- the best medical evidence for the safety and the efficacy of the product, the product

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design and the way people implant it. So that is what -- that is my motivation for being here. It's not to support Ethicon.
Q. Okay.
MR. TEAGUE: I'm going to reserve the rest of my time. Do you have any follow-up questions at this point? If not, I'll just keep going, but -- what am I at right now --
MR. ROSENBLATT: Actually, I --
MR. TEAGUE: -- by your clock?
MR. ROSENBLATT: 2:52.
MR. TEAGUE: Okay. Okay. I'll tell you what then --
MR. ROSENBLATT: Let me ask just -- I think I have one question maybe.
Okay. I'm ready. Oh, I'm sorry. Are you ready, Matt?
MR. TEAGUE: Yeah, I'm sorry, go ahead.
EXAMINATION
BY MR. ROSENBLATT:
Q. Doctor, is pain a potential complication that is unique to TVT?

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A. It's actually not unique to TVT. It's a well known complication of any surgical procedure for stress urinary incontinence.
MR. ROSENBLATT: No further questions.
MR. TEAGUE: Okay. I think I'm pretty much done. Let me just -- if you don't mind, let me review for a second.
We can go off the record.
(Recess taken.)
THE VIDEOGRAPHER: This is the end of Videotape No. 3 in the deposition of Catherine Matthews, MD. The time is 2:31 p.m. We are off the record.
(Deposition Adjourned at 2:31 p.m.)

REPORTER'S CERTIFICATE

I, LESHAUNDA CASS-BYRD, CSR No. B-2291, RPR, Registered Professional Reporter, certify that the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony of the witness, the questions propounded, and all objections and statements made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That the foregoing is a true and correct transcript of my shorthand notes to taken.

I further certify that I am not a relative or employee of any attorney or the parties, nor financially interested in the action.

I declare under penalty of perjury under the laws of North Carolina that the foregoing is true and correct.

Dated this March 29, 2016.

LESHAUNDA CASS-BYRD, CCR-B-2291, RPR

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____
CATHERINE A. MATTHEWS, M.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.
My commission expires:_____

_____
Notary Public